



# Evaluation of the Indiana Medicaid Preferred Drug List (PDL) Program

# FINAL Report #5

PERIOD EVALUATED: 10-1-05 to 3-31-06

Presented by:

**ACS Government Healthcare Solutions** 

For State of Indiana Office of Medicaid Policy and Planning And Indiana Medicaid DUR Board

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# **EXECUTIVE SUMMARY**

#### Introduction

The cost of providing prescription drug services for traditional Medicaid fee-for-service (FFS) recipients has risen dramatically. Even so, the Indiana General Assembly, the Office of Medicaid Policy and Planning (OMPP), and the Indiana Medicaid Drug Utilization Review (DUR) Board have demonstrated an unwavering commitment to address the health care needs of the residents of Indiana. A major focus for the OMPP and Medicaid DUR Board has been to maximize prescription drug products/services while minimizing the cost to the State of Indiana.

In January 2002, the State of Indiana created a prior authorization (PA) program called the Indiana Rational Drug Program (IRDP). The program was designed to control costs while ensuring appropriate use of prescription drugs for Medicaid recipients. *Indiana Senate Enrolled Act No.* 228 (SEA 228) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid, with prior authorization for drugs not included on the PDL. The PDL program was built upon the intent of the IRDP, but it encompassed a much wider range of prescription drug classes. As with the IRDP, the purpose of the PDL is to ensure that Indiana Medicaid recipients receive clinically appropriate prescription drugs, while minimizing the cost incurred. The PDL program was introduced in August 2002 for the Primary Care Case Management (PCCM) Program and the Fee-for-Service Program.

The PDL selection process is based upon a non-biased clinical review of each medication within a given therapeutic class. The Indiana Medicaid Therapeutics Committee (T Committee), composed of physicians and pharmacists, reviews and submits selection recommendations to the Indiana Medicaid Drug Utilization Review (DUR) Board for approval. In finalizing selection of one or more preferred drugs within a therapeutic class, the T Committee and DUR Board give primary consideration to clinical efficacy or therapeutic appropriateness. They then examine cost<sup>1</sup>, including consideration of the PDL program's fiscal implications on other components of the State's Medicaid program. Other components include access to care and potential cost shifting. The medications classified as "non-preferred" may be permitted upon request from the prescribing physician using the published prior authorization process.

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<sup>&</sup>lt;sup>1</sup> Cost is net of federal and supplemental rebates.

The first year of the Indiana PDL program consisted of more than 52 therapeutic drug classes implemented over a 13-month period beginning in August 2002<sup>2</sup>. After the first year of phased-in implementations of therapeutic classes, a process of continual improvement to the PDL program began in September 2003, with biannual reviews of PDL classes.

Indiana SEA 228 also provided for evaluation of health outcomes and cost implications of the PDL program. Therefore, an initial evaluation of the health outcomes and cost implications of the Indiana PDL Program after its first year of implementation was conducted by ACS Government Healthcare Solutions using prescription and medical data from August 2002 to August 2003. The report, containing outcomes evaluation of the PDL program and recommendations for improvement, was submitted to the DUR Board in May 2004.

ACS Government Healthcare Solutions produced a second report, Report #2, as a followup evaluation on the health outcomes and cost implications of the Indiana PDL program. Report #2 evaluated the 2<sup>nd</sup> year of the PDL program operations using prescription and medical data from October 2003 to September 2004. Report #2 evaluated 54 therapeutic classes either re-reviewed or newly implemented changes by the T Committee and DUR Board in the 2<sup>nd</sup> year of the PDL program. The follow-up outcomes evaluation and additional recommendations for improvement was submitted to the DUR Board in June 2005.

Both Reports #1 and #2 contained a recommendation to add supplemental rebates as part of the PDL program. States who wish to pursue Medicaid supplemental rebates, in addition to rebates already received under the National Drug Rebate Agreement, have the option to negotiate such rebates with drug manufacturers as specified in Federal law. Rebates received under state supplemental agreements are shared with the Federal government at the same rate as the national or federal rebates. The manufacturers' federal and supplemental rebates are compiled and presented to the T Committee, along with clinical drug information. The T Committee then makes recommendations to the DUR board based upon these economic and clinical factors as to which products should be designated as "preferred". Supplemental rebates were phased-in to the PDL program with some therapeutic classes starting October 26, 2004 and a second group on December 21, 2004.

prescription and OTC drugs were considered two separate therapeutic class groupings. More than 52 therapeutic drug classes were implemented; however, some classes were combined due to lack of claims for analysis at 13-months post-implementation. Later, in Years 2 and 3, as data accumulated, these classes were split into their own First Data Bank<sup>TM</sup> therapeutic class. Additionally, in Years 2 and 3, some classes were reclassified and split into two or more classes by First Data Bank<sup>TM</sup> Therefore, 52 classes were evaluated in the first PDL report (12 months post-implementation), 54 classes were evaluated in PDL Report #2 (13-24 months post-implementation), 62 classes were evaluated in PDL Report #3 (26-31 months post-implementation), 67 classes were evaluated in PDL Report #4 (32-37 months postimplementation) and 65 classes were evaluated in PDL Report #5 (38-43 months post-implementation).

<sup>&</sup>lt;sup>2</sup> First Data Bank's TM definition of a "therapeutic class" was used to operationally define the drugs belonging to or grouped within a "therapeutic class" for all PDL evaluation reports. Furthermore, some therapeutic classes had both prescription vs. OTC drugs within the class. For ease of evaluation,

As prescription and medical data became available, ACS Government Healthcare Solutions' PBM clinical group began evaluation of, and reporting on, each 6-month interval as additional follow-up on the health outcomes and cost implications of the Indiana PDL program. Reports #3, #4 and #5 are each 6-month follow-up evaluations.

Report #3 evaluated PDL program operations using prescription and medical data from October 1, 2004 to March 31, 2005. Report #3 evaluated 62 therapeutic classes either rereviewed or newly implemented changes by the T Committee and DUR Board in the first half of Year 3 of the PDL program (approximately 2 to 2 ½ years or from 26 to 31 months after PDL program operations first began). The follow-up outcomes evaluation and additional recommendations for improvement was submitted to the DUR Board in December 2005. Report #3 included analyses of initial savings resulting from the phased-in addition of supplemental rebates to the PDL program in addition to the original legislative requirements listed in the objectives below.

Report #4 evaluated PDL program operations using prescription and medical data from April 1, 2005 to September 30, 2005. Report #4 evaluated 67 therapeutic classes in the second half of Year 3 (from approximately 2 ½ to 3 years into PDL program operations, or from 32 to 37 months) after PDL program operations first began. Report #4 included continued analyses of savings resulting from supplemental rebates in addition to the original legislative requirements listed in the objectives below.

Report #5 evaluated PDL program operations using prescription and medical data from October 1, 2005 to March 31, 2006. Report #5 evaluated 65 therapeutic classes in the first half of Year 4 (from approximately 3 to 3 ½ years into PDL program operations, or from 38 to 43 months) after PDL program operations first began. Report #5 included continued analyses of savings resulting from supplemental rebates in addition to the original legislative requirements listed in the objectives below.

# **Objectives**

The goal of this report is to determine the overall impact of the PDL in accordance with Indiana Code 12-15-35-28(h). The four primary objectives are to evaluate:

- 1.) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.
- 2.) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.
- 3.) The number of times prior authorization was requested, and the number of times prior authorization was: (A) approved and (B) disapproved.
- 4.) The cost of administering the preferred drug list.

# **Results Summary**

# 1.) Impact of the Preferred Drug List on Medicaid Medical Costs

Of the therapeutic classes evaluated, overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation). It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned to take preferred or non-preferred drugs; therefore, only association or lack of association can be determined. Sample sizes were measured in number of recipients (n=38,724 recipients in Year 1; 23,585 recipients in Year 2; 21,127 recipients in the first half of Year 3; 33,312 recipients in the second half of Year 3; and, 13,554 recipients in the first half of Year 4).

Inclusion/exclusion criteria were applied to all therapeutic classes in the PDL list as shown in Figure E.1.

#### Figure E.1. Inclusion/Exclusion Criteria for Therapeutic Classes Studied in the Medical Analyses

Therapeutic classes chosen for <u>inclusion</u> in studying medical data were:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, recipients taking medications only in therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report #1. These same recipients in the original 8 therapeutic classes (who were still eligible) were subsequently followed-up in the 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> reports, along with additional classes that met the inclusion criteria
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation.
   A relatively large market shift was defined as therapeutic classes with 95% or less preferred market share prior to PDL program implementation.
- Therapeutic classes with approved use as long-term maintenance therapy for chronic illnesses. This
  maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or nonpreferred drugs for a long, continuous time period. Long-term maintenance therapy increases the likelihood
  of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

Therapeutic classes excluded from medical data analyses were:

- Therapeutic classes with greater than 95% preferred drug market share prior to the PDL implementation.
   These classes were excluded due to an insufficient number of recipients who switched from non-preferred to preferred in order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it would be impossible to determine if medical expenditures are associated with taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.
- Therapeutic classes with too few recipients taking the medications. The sample size of each therapeutic class must be large enough to obtain statistical significance ( $\alpha = 0.05$  with a medium effect size) with reasonable power (.80).

After applying the inclusion/exclusion criteria, recipients taking medications from eight therapeutic classes were evaluated in Reports #1 and #2 for differences in total and specific medical expenditures. These eight therapeutic classes were: ACE Inhibitors, Alpha/beta Adrenergic Blocker Antihypertensives, Calcium Channel Blocker

Antihypertensives, Loop diuretics, Platelet Aggregation Inhibitors, Thiazolidinediones, Triptans, and Proton Pump Inhibitors.

Recipients receiving medications from one or more of these eight therapeutic drug classes were evaluated over a 6-month pre- and a 6-month post-implementation of the PDL program in Report #1. Report #2 then evaluated those recipients' medical expenditures through the end of Year 2 post-PDL. Report #3 continued to follow medical expenditures of recipients from the original eight classes. Furthermore, three additional classes met the inclusion criteria and were included for evaluation of medical expenses. The three new therapeutic classes for Report #3 where recipients' medical expenses were evaluated are: Miotics, Antipsoriatics, and Urinary Antispasmotics/Anti-incontinence drugs.

Report #4 evaluated recipients' medical expenditures of the original therapeutic classes from Reports #1, #2, and #3 that contained large enough recipient sample sizes to evaluate at 37 months post-implementation. Furthermore, one additional class met the inclusion criteria and was included for evaluation of medical expenses. The six therapeutic classes evaluated were: ACE Inhibitors, Fibric Acids, Platelet Aggregation Inhibitors, Thiazolidinediones, Miotics, and Urinary Antispasmotics/Anti-incontinence drugs.

Report #5 evaluated recipients' medical expenditures of the original therapeutic classes from Reports #1, #2, and #3 that contained large enough recipient sample sizes to evaluate at 43 months post-implementation, plus the additional class that met the inclusion criteria in Report #4 was also included for evaluation of medical expenses. The ten therapeutic classes evaluated were: ACE Inhibitor Antihypertensives, Angiotensin Receptor Blockers (ARB) Antihypertensives, Calcium Channel Blocker Antihypertensives, Bile Acid Sequestrants, Fibric Acids, Platelet Aggregation Inhibitors, Thiazolidinediones, SERM's/Bone Resorption Suppression drugs, Miotics, and Urinary Antispasmotics/Anti-incontinence drugs.

#### **KEY OBSERVATIONS:**

Of all the therapeutic classes evaluated, the evidence does not demonstrate any statistically significant change in overall medical expenditures at 12, 25, 31, 37, and 43 months after PDL implementation. In other words, recipients affected by the PDL program were not associated with a statistically significant difference in overall medical expenditures when compared to recipients not affected by the PDL program.

Analyses were performed on specific medical expenditures in addition to overall medical expenditures. Specific medical service type expenditures analyzed were: prescriber office visits, inpatient hospital admissions, emergency room services, and laboratory procedures. When examining specific medical service types at 12, 25, 31, 37 and 43 months after PDL implementation of a therapeutic class, there is no evidence to suggest that specific medical costs (e.g. other health care providers, lab, emergency room services

or hospital services) are higher on a wide, systematic scale for recipients switched to taking preferred drugs or already taking preferred drugs versus recipients taking non-preferred drugs.

#### 2.) Impact of PDL on Medicaid Recipients' Ability to Obtain Prescription Drugs

#### Recipients Followed for 30 Davs after a Denied Claim

Recipients affected by the PDL program would be those taking a non-preferred medication before PDL implementation. Affected recipients would then either have:

- switched to a preferred medication;
- received a prior authorization to continue with their non-preferred medication;
- switched to a preferred medication for a short period then switched back to a non-preferred medication, or
- stopped taking their medication (either due to experiencing a denied claim at the pharmacy or, due to the fact that the medication was no longer needed).
- or, dropped out of the analysis because they were no longer eligible and no longer received medications through the Medicaid program.

#### Report #1 Evaluation

In Report #1, 23 classes contained enough claims data 12 months after PDL implementation to assess the PDL program's impact on users' access to medications. Of the 188,508 monthly recipients followed 12 months after the initial PDL program began, only 1,485 (0.78%) experienced a denied claim with no paid claim for a related medication within 30 days. It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies.

# Report #3 Evaluation

In Report #3, the PDL program's impact on users' access to medications after the PDL program had been operating for a long time period was assessed. Retail pharmacy prescription claims were examined at 26 and 31 months after initial implementation. Since nursing home claims were sometimes billed months after the date of service, only outpatient retail pharmacy claims conducted at point-of-sale were analyzed. Of the 203,463 monthly recipients followed for 26-months after, and of the 208,693 monthly recipients followed for 31-months after the initial PDL program began, only 3,288 (1.5%) experienced a denied claim in the two months of October 2004 and March 2005.

A random sample of 1,000 retail pharmacy Medicaid recipients' claims were analyzed during the month of October 2004 after the recipient experienced a denied claim due to a non-PDL prescription claim. Another random sample of 750 was analyzed in the month of March 2005. Of the 1,750 recipients followed from the initial claim rejection due to a non-PDL prescription claim, only 47 recipients (0.023%) in October 2004 and 28 recipients (0.013%) in March 2005 experienced a denied claim with no paid claim for a related medication within the next 30 days.

#### Report #4 Evaluation

Report #4 evaluated the period from April 1, 2005 to September 30, 2005. During this 6month period, 198,479 claims denied for 55,241 recipients due to a non-PDL edit. Many of these claims were repeated submissions by the pharmacy of the same drug on the same day. Meaning, the rate of recipients who were truly denied medication due to a non-PDL edit was significantly lower. To determine the true rate, the PDL program's impact on users' access to medications after the PDL program had been operating for 37 months was assessed. Medicaid recipients' claims were followed during the month of September 2005. This time, analysis focused on two therapeutic classes of maintenance medications both antihypertensive drugs – angiotensin converting enzyme Inhibitors (ACE Inhibitors) and angiotensin receptor blockers (ARBs). Only 107 recipients experienced a claim rejection due to a non-PDL ACE Inhibitor prescription claim, and 194 recipients experienced a claim rejection due to a non-PDL ARB. Of the 107 recipients who experienced a claim rejection due to non-PDL ACE Inhibitors, only two recipients experienced a denied claim with no paid claim for a related medication within the next 30 days. Of the 194 recipients who experienced a claim rejection due to non-PDL ARBs, only two recipients (1.03%) experienced a denied claim with no paid claim for a related medication within the next 30 to 180 days.

It is impossible, with such a small sample of two within each therapeutic class, to conclude whether these recipients were simply aberrations and no longer needed the antihypertensive medication, or whether the two recipients' access to care was really impaired. Both recipients received medications for other problems after experiencing a denied claim for a non-PDL ACE inhibitor. So, it would seem plausible that these recipients still had access to care for antihypertensive as well as other treatments and were possibly were not adherent with their antihypertensive therapy or no longer needed the antihypertensive drug.

#### Report #5 Evaluation

Report #5 evaluated the period from October 1, 2005 to March 31, 2006. During this 6-month period, 101,163 claims denied for 33,911 recipients due to a non-PDL edit. Many of these claims were repeated submissions by the pharmacy of the same drug on the same day. Meaning, the rate of recipients who were truly denied medication due to a non-PDL edit was significantly lower. To try to determine more accurately the PDL program's impact on users' access to medications, Medicaid recipients' claims were followed during the month of January 2006 for 15 therapeutic classes of maintenance medications. The 15 therapeutic classes of maintenance medications were: antihypertensive drugs (angiotensin converting enzyme inhibitors [ACE inhibitors], angiotensin receptor blockers [ARBs], calcium channel blockers [CCB], ACE inhibitors with CCB, beta blockers, and alpha & beta blockers); thiazolidinediones; alpha adrenergic blockers; triptans; platelet aggregation inhibitors; miotics/other intraocular pressure reducers; urinary tract antispasmotic/anti-incontinence agents; and antipsoriatics.

Of the 15 therapeutic classes in the month of January 2006, a total of 27,656 unique recipients had paid and denied claims. For January 2006, 27,398 recipients (99.1%) had paid claims and only 258 recipients (0.9%) experienced a denial. Twenty-six of the 258 recipients experienced a denied claim with no subsequent paid claim because they were

no longer eligible. Of 232 (0.84% of 27,656) recipients still eligible and who experienced a denied claim, 35 (0.13%) recipients did not have a subsequent paid claim and 197 (0.71%) recipients had a subsequent paid claim. Of the 197 recipients (who had a subsequent paid claim, 163 (83% of 197 and 0.59% of total recipients) received a paid claim within 24 hours to 30 days after the PDL exception denial hit. Over 95% of the 163 recipients who had exceptions with subsequent paid claims were getting early fills of medication; therefore, if recipients received the medication within 30 days of the PDL exception, there should be no break or stoppage in taking therapy due to lack of access to medications. Of the 197 recipients who experienced a PDL exception (denial) and who had a subsequent paid claim, 34 (17% of 197 and 0.12% of total recipients) received a paid claim within 31 to 180 days of the denial.

The 34 (0.12%) recipients who experienced a denial with a subsequent paid claim 31 to 180 days later may have experienced a delay in taking medication. There is also possibility that some of these recipients had samples or other medications at home and therefore didn't request the medication again until they needed it. Of the 35 (0.13%) recipients who did not have a subsequent paid claim, it is impossible to determine how many may have gotten their medications through the Medicare D program and how many may no longer have needed the maintenance medication.

Overall, the initial number of recipients who may have experienced a delay in receiving needed medications (0.78% without a related claim within 30 days of the denial in the first year) suggests a minimum impact on PDL users. Further, denials diminished monthly as providers gained experience with the program as evidenced by the 0.023% at 26 months and 0.013% at 31 months after the program began.

Finally, in January 2006 even with the confusion of Medicare D implementation, the number of Medicaid recipients who may have experienced a delay in receiving medications (0.12% without a related claim within 30 days of the denial and 0.13% without a related Medicaid paid claim for a total of 0.25%) suggests a minimum impact on PDL users.

#### **Adherence Study**

It is impossible to know from pharmacy administrative claims data what portion of dropped claims were duplicate or unnecessary therapies. Dropped claims are defined as recipients experiencing a denied claim for a non-PDL drug and received no other drug within 30 to 180 days afterward. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. Claims data does not allow full explanation for the therapy interruptions. For example, there are many potential reasons other than PDL such as: physician sampling of medications, other 3<sup>rd</sup> party liability, patient adherence, or changes in patient therapy.

To put this into perspective, the rate of non-preferred claims denials where recipients had no later related claim within the next 30-days is far lower than the 30 to 50% non-

adherence rate after receiving medications documented in the literature. Since between 30 to 50% of all patients fail to follow their prescribed therapy once they receive it, non-adherence or lack of persistence with taking medications may be a larger concern. Therefore, analysis in Report #2 examined recipients who were non-adherent (as evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

# **KEY OBSERVATIONS:**

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were non-adherent. The results illustrate that the problem with recipients' health outcomes for Indiana recipients are less likely to be related to whether recipients are taking non-preferred or preferred medications, but rather are more likely to be related to whether recipients will be adherent with taking any prescribed medication, whether it is preferred or non-preferred.

# 3.) Number of Times Prior Authorization was Requested, Approved and Disapproved.

During the first six months of federal fiscal year 2006 (10/1/05 to 3/31/06) there were 19,073 PDL program prior authorizations requested. Of the 19,073 PAs requested, 18,978 were approved (99.5%), 77 were disapproved (0.4%) and 18 were suspended (0.1%).

The percentage of prior authorizations (PAs) for non-preferred drugs that were disapproved slightly increased over the three-and-one-half year span from 0.2% PAs disapproved (between August 2002 to December 2002 when the PDL program first began) to peaking at 1.6% PAs disapproved for FFY 2004. Then the percentage of prior authorizations (PAs) for non-preferred drugs that were disapproved slightly decreased again after its peak in FFY 2004 to 0.4% PAs disapproved in the first half of 2006.

Table E.2. Preferred Drug List Prior Authorization Requests

Time Period	Average # Utilizers per Month	Total All PAs Requested	Ap- proved	% Ap- proved **	# Ap- proved PUPM*	De- nied	% De- nied	Sus- pended	% Sus- pended
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	204,840	80,950	79,200	97.8%	0.0322	193	0.2%	1,557	1.9%
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	208,995	75,705	73,681	97.3%	0.0294	1,177	1.6%	847	1.1%
First 6 months - FFY 2005 (Oct 1, 2004 to Mar 31, 2005)	205,982	41,052	40,427	98.5%	0.0327	513	1.2%	112	0.3%
Last 6-months of FFY 2005 (Apr 1, 2005 to Sep 30, 2005) 2 <sup>nd</sup> Half of Year 3 – Report #4	185,932	30,420	30,072	98.9%	0.0270	312	1.0%	36	0.1%
First 6 months - FFY 2006 (Oct 1, 2005 to Mar 31, 2006) 1 <sup>ST</sup> Half of Year 4 – Report #5	129,790	19,073	18,978	99.5%	0.0244	77	0.4%	18	0.1%

<sup>\*</sup> Per utilizer per month (PUPM)

11/20/2006

#### \*\* RECOMMENDED ACTION:

- The Office notes that the 99.5% approval rate for non-preferred medications is of concern, and as such, requests the DUR Board's review of the criteria used for prior authorization determinations.
- The Office requests that the DUR Board review the recommendations beginning on page 24 and provide the Office with the DUR Board's recommendations on same.
- The Office solicits any other ideas or recommendations by the DUR Board for improving the current prior authorization criteria.

# 4.A) Net Pharmacy Benefit Savings Associated with the PDL Program

#### Report Period One: 8/1/02 to 7/31/03 Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 8/1/02 to 7/31/03 were an estimated \$642³ million (Chart E.1). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable PDL Classes with Potential to Affect Change (24%) = \$154 M
- AAAX<sup>4</sup> (considered preferred per statute) (31.1%) = \$200 M
- Classes Not Reviewed<sup>5</sup> (27%) = \$173 M
- PDL classes with limited benefit @ >95% preferred prior to implementation (18%) = \$116 M

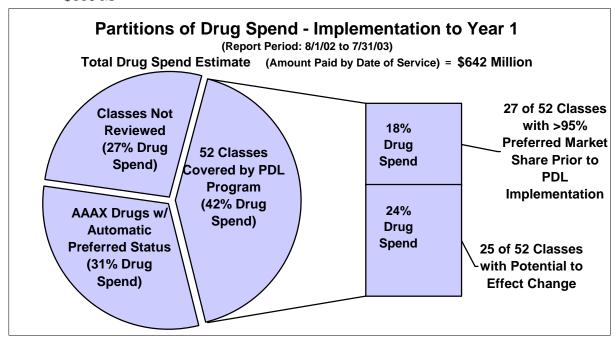


Chart E.1 Partitions of Total Drug Spend (\$642 Million) from 8/1/02 to 7/31/03 Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit <u>net</u> savings (after CMS [standard Federal] rebate deductions after market share shifts and cost to administer the PDL program) in the **52 PDL classes implemented and evaluated from August 2002 to September 2003** (Year 1 post-PDL implementation) were estimated to be **\$7.78 million**.

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<sup>&</sup>lt;sup>3</sup> Estimates are from 8/1/02 to 7/31/03 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).

<sup>&</sup>lt;sup>4</sup> These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

<sup>&</sup>lt;sup>5</sup> Drug classes of medications not on the PDL program from August 2002 to August 2003.

<sup>&</sup>lt;sup>6</sup> Over 95% of market share were preferred medications prior to implementation.

# Report Period Two: 10/1/03 to 9/30/04 (FFY 2004) Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/03 to 9/30/04 were an estimated \$736<sup>7</sup> million (Chart E.2). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable PDL Classes with Potential to Affect Change (14%)= \$103 M
- $AAAX^8$  (considered preferred per statute) (31.1%) = \$229 M
- Classes Not Reviewed (28.2%) = \$208 M
- PDL classes with limited benefit @ >95% preferred prior to implementation (26.6%) = \$196 M

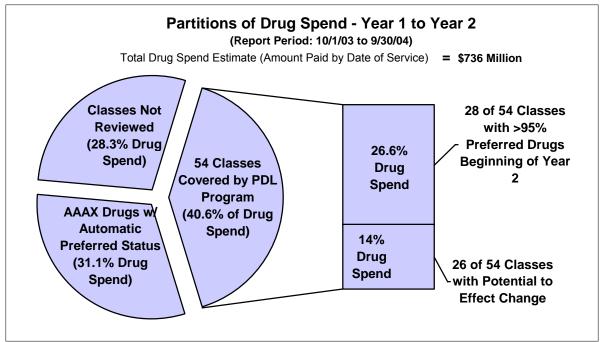


Chart E.2 Partitions of Total Drug Spend (\$736 Million) from 10/1/03 to 9/30/04 Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) due to market share shifts in the 54 PDL classes implemented and evaluated beginning in August 2002 are estimated to be \$7.78 million in Year 1, and an additional \$175,000 in Year 2 with two additional classes added to the analysis.

<sup>&</sup>lt;sup>7</sup> Estimates are from 10/1/03 to 9/30/04 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).

<sup>&</sup>lt;sup>8</sup> These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

<sup>&</sup>lt;sup>9</sup> Drug classes of medications not on the PDL program from October 2003 to September 2004.

<sup>&</sup>lt;sup>10</sup> Over 95% of market share were preferred drugs at beginning of Year 2.

# Report Period Three: 10/1/04 to 3/31/05 Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/04 to 3/31/05 were an estimated \$392<sup>11</sup> million (Chart E.3). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable –PDL Classes with Potential to Affect Change (14.7%)=\$57.4 M
- PDL classes with limited<sup>12</sup> benefit @ >95% preferred prior to implementation (22.3%) = \$87.6 M
- $AAAX^{13}$  (considered preferred per statute) (30.4%) = \$119 M
- Classes Not Reviewed<sup>14</sup>  $(32.6\%^{15}) = $128 \text{ M}$

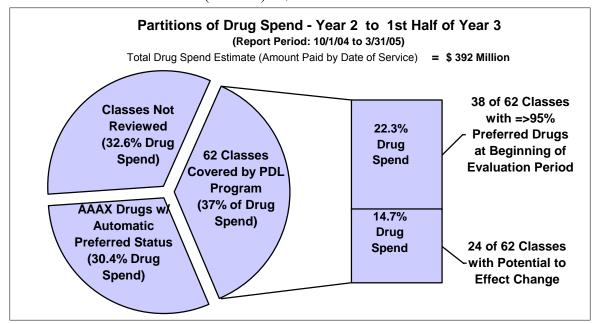


Chart E.3 Partitions of Total Drug Spend (\$392 Million) from 10/1/04 to 3/31/05 Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be an additional \$1.25 million for the first half of Year 3 (October 2004 through March 2005) with 62 PDL classes (8 additional classes added to the analysis).

<sup>&</sup>lt;sup>11</sup> Estimates are from 10/1/04 to 3/31/05 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).

12 Over 95% of market share were preferred drugs at the beginning of Year 3.

<sup>&</sup>lt;sup>13</sup> These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

<sup>&</sup>lt;sup>14</sup> Drug classes of medications not on the PDL program from October 2004 to March 2005.

<sup>&</sup>lt;sup>15</sup> Expenditures for classes not reviewed grew as a percentage of total spending from Year 2 to the first half of Year 3 because many new drugs with high prices came onto market that had not yet been reviewed.

# Report Period Four: 4/1/05 to 9/30/05 Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 4/1/05 to 9/30/05 were an estimated \$354.5<sup>16</sup> million (Chart E.4). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable –PDL Classes with Potential to Affect Change (10.8%)=\$38.1 M
- PDL classes with limited<sup>17</sup> benefit @ >95% preferred prior to implementation (25.4%) = \$90.2 M
- AAAX<sup>18</sup> (considered preferred per statute) (30.6%) = \$108 M
- Classes Not Reviewed<sup>19</sup>  $(33.2\%^{20}) = $117.7 \text{ M}$

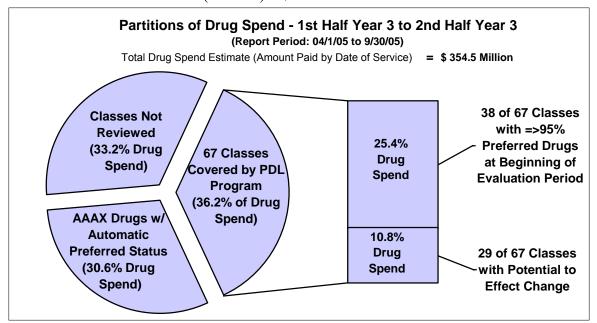


Chart E.4 Partitions of Total Drug Spend (\$354.5 Million) from 4/1/05 to 9/30/05 Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be an additional \$8.60 million for the second half of Year 3 (April 2005 through September 2005) with 67 **PDL classes** (5 additional classes added to the analysis from Study 3 to 4).

<sup>&</sup>lt;sup>16</sup> Estimates are from 04/1/05 to 9/30/05 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).

<sup>17</sup> Over 95% of market share were preferred drugs at the beginning of the second half of Year 3.

<sup>&</sup>lt;sup>18</sup> These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

<sup>&</sup>lt;sup>19</sup> Drug classes of medications not on the PDL program from April 2005 to September 2005.

<sup>&</sup>lt;sup>20</sup> Expenditures for classes not reviewed grew as a percentage of total spending from the first to second half of Year 3 because many new drugs with high prices came onto market that had not yet been reviewed.

# Report Period Five: 10/1/05 to 3/31/06 Partitions of Drug Spend

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/05 to 3/31/06 was an estimated \$254.6<sup>21</sup> million (Chart E.5). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable –PDL Classes with Potential to Affect Change (9.4%)=\$23.86 M
- PDL classes with limited<sup>22</sup> benefit @ >95% preferred prior to implementation (25.0%) = \$63.8 M
- AAAX<sup>23</sup> (considered preferred per statute) (38.9%) = \$99 M
- Classes Not Reviewed<sup>24</sup>  $(26.7\%^{25}) = $67.9 \text{ M}$

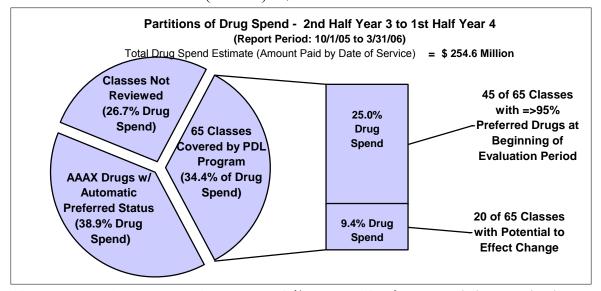


Chart E.5 Partitions of Total Drug Spend (\$254.6 Million) from 10/1/05 to 3/31/06 Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit <u>net</u> savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be <u>an additional</u> \$2.27 million for the first half of Year 4 (October 2005 through March 2006) with 65 PDL classes (1 class was split into two & 3 classes no longer reviewed from Study 4 to 5).

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<sup>&</sup>lt;sup>21</sup> Estimates are from 10/1/05 to 3/31/06 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees). Also note there was expenditure shifting due to Medicare Part D drug program implementation on 1/1/06.

<sup>&</sup>lt;sup>22</sup> Over 95% of market share were preferred drugs at the beginning of the first half of Year 4.

These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

<sup>&</sup>lt;sup>24</sup> Drug classes of medications not on the PDL program from October 2005 to March 2006.

<sup>&</sup>lt;sup>25</sup> Expenditures for classes not reviewed decreased as a percentage of total spending from the 2<sup>nd</sup> half of Year 3 to the 1<sup>st</sup> half of Year 4 because less new drugs with high prices came onto market that had not yet been reviewed, and drugs that had come into the market in Years 2 & 3 had been reviewed.

#### Summary of Net Savings Estimates for All Reports: 8/1/02 to 3/31/06

Table E.3 depicts the total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) for each time period evaluated and over the entire 3.5-year period.

Table E.3 Number of Classes, Rebate Shifts & Estimated Savings<sup>26</sup>

Time Period	# Classes Affected by the PDL Program	Total Estimated Savings from Market Share Shifts <sup>27</sup> before Rebates	Total Estimated Rebate Shifts	Total Net Savings <sup>28</sup> Estimates Minus Federal Rebate Estimates	Estimated Cost of Administering the PDL	Total Net Savings <sup>29</sup> Estimates Minus Rebates & Estimated Cost of Administering the PDL
Year 1 (8/1/02 to 7/31/03)	52	\$12.4 million	- \$3,524,829	\$8.9 million	-\$1.125 million	\$7.78 million
Year 2 (10/1/03 to 9/30/04)	54	\$2.06 million	- \$ 931,105	\$1.13 million	-\$1.125 million	\$ 175,000
1 <sup>st</sup> half Year 3 (10/1/04 to 3/31/05)	62	\$1.99 million	- \$ 130,139	\$1.86 million	-\$614,000	\$1.25 million
2 <sup>nd</sup> half Year 3 (4/1/05 to 9/30/05)	67	\$ 10.96 million	- \$1,731,412	\$9.23 million	-\$627,500	\$8.60 million †
1 <sup>st</sup> half Year 4 (10/1/05 to 3/31/06)	65**	\$4.53 million	-1,589,078	\$2.94 million	-\$675,000	\$2.27 million
SubTotal		\$31.94 million	\$7,906,563 million	\$24.06 million	-\$4.165 million	\$19.9 million
	-					
Supplementa	Supplemental Rebate Savings (10/1/04 to 3/31/05) \$6.08 million*					
Supplemental Rebate Savings (4/1/05 to 9/30/05) \$7.81 million				on	+ \$21.48 Million	
Supplemental Rebate Savings (10/1/05 to 3/31/06) \$ 7.59 million				on		
GRAND TOTAL Net Savings (for 3.5 years since implementation) →				\$41	I.38 Million	

All savings and net savings are estimated.Estimates include both state and federal share.

<sup>&</sup>lt;sup>28</sup> Estimates include both state and federal share.

<sup>&</sup>lt;sup>29</sup> Estimates include both state and federal share.

Report #3 reported supplemental rebate savings as \$6.81 million. After all adjustments were made, the supplemental rebate savings changed to \$6.08 million; therefore, supplemental rebate savings were adjusted accordingly in Report #4.

Total therapeutic classes reviewed dropped from 67 to 65 classes because one class was split into two classes & three classes were no longer reviewed from Study 4 to 5).

# †Reason for Increased Savings from 1st Half to 2nd Half of Year 3†

The large increase in net savings from the first half of Year 3 to the 2<sup>nd</sup> half of Year 3 illustrated in Table E.3 was attributable to two factors: 1.) Federal CMS rebate savings resulting from large changes in the PDL program; and, 2.) Savings resulting from less utilization due to implementation of step edits and quantity limits. Most of the savings came from a few classes. For example, the 'Brand Name Narcotics' therapeutic category jumped from 92.4% preferred to 99.3% preferred. Additionally generic oxycodone ER 80mg and fentanyl patches were placed on the preferred list while Palladone® was placed on the non-preferred list. Fentanyl was limited to 10 patches per 30 days, and a step edit was added to Palladone® (which was removed from market in mid-July). Step edits, quantity limits and shifting of agents on the PDL list resulted in a net savings of approximately \$5.5 million dollars in this one Narcotics therapeutic class alone.

A similar situation occurred with the gastrointestinal (GI) agents therapeutic class, 'Proton Pump Inhibitors (PPIs).' Omeprazole switched from prescription to an over-the-counter drug and a step therapy edit was implemented requiring new patients to try an H-2 blocker or OTC Prilosec® prior to receiving a preferred PPI. Prevacid® changed from PDL neutral to non-preferred; while a step therapy edit was implemented with a quantity limit of one capsule per day for Nexium®. Step edits, quantity limits and shifting of agents on the PDL list resulted in a net savings of approximately \$3.5 million dollars in the GI therapeutic category.

Finally, the 'Non-sedating Antihistamines' therapeutic class had several changes. Allegra® was switched to non-preferred; step edits were added so that patients must fail a trial of OTC loratadine before obtaining other non-sedating antihistamines whether preferred or non-preferred; and, quantity limits were implemented for the non-preferred drug Allegra®. Step edits, quantity limits and shifting of agents on the PDL list resulted in a net savings of approximately \$1.4 million dollars in Non-Sedating Antihistamine therapeutic class.

In sum, changes from preferred to non-preferred created shifts in net CMS rebates resulting in savings. Additionally, step therapy edits and quantity limits have resulted in substantial savings by less utilization of expensive drugs.

#### **Total Net Savings**

The total annualized pharmacy benefit <u>net</u> savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) in the 52 PDL classes implemented in August 2002 through July 2003 were estimated to be \$7.78 million through Year 1, with an additional \$175,000 estimated net savings through Year 2 with 54 PDL classes evaluated. In the 62 PDL classes evaluated from October 2004 through March 2005, pharmacy benefit <u>net</u> savings were estimated to be an additional \$1.25 million through Year 2.5, plus an additional estimated savings of \$6.08 million from supplemental rebates added to the program beginning in October 2004. In the 67 PDL classes evaluated from April 2005 through September 2005, pharmacy benefit <u>net</u> savings were

estimated to be an additional **\$8.6** million through the second half of Year 3; plus, additional estimated savings of **\$7.81** million from supplemental rebates for April to September 2005. In the **65** PDL classes evaluated from October 2005 through March 2006, pharmacy benefit <u>net</u> savings were estimated to be an additional **\$2.27** million through the first half of Year 4; plus, additional estimated savings of **\$7.59** million from supplemental rebates for October 2005 to March 2006.

# **KEY OBSERVATION of PDL SAVINGS SUMMARY:**

Over the entire 3.5-year PDL program, the overall <u>net</u> pharmacy savings is estimated to be \$19.9 million plus \$21.48 million in estimated supplemental rebates for a total estimated savings of \$41.38 million.

#### Number of Classes with Little Opportunity for Market Share Shifts and Subsequent Savings

In 27 of 52 PDL classes studied in Year  $1^{30}$ , in 28 of 54 PDL classes studied in Year 2, in 38 of 62 PDL classes studied in the  $1^{st}$  half of Year 3, 38 of 67 PDL classes studied in the  $2^{nd}$  half of Year 3, and 45 of 65 PDL classes studied in the  $1^{st}$  half of Year 4, preferred drugs selected by the Indiana Medicaid Therapeutics Committee and accepted by the DUR Board did not provide opportunity for either any or very limited market share change because either <u>all</u> drugs or  $\geq 95\%$  of drugs within the class were selected as preferred, or because <u>utilization</u> in the class was already greater than 95% preferred, but less than 100% preferred.

Table E.4 Number of Classes Reviewed and Percent Preferred - Year 1

# Classes	Year 1 Results	% Before Implementation	% Preferred End of Year 1
52	TOTAL ALL PDL PROGRAMS	75.2%	95.8%
27	Totals for Classes With Only Limited Potential For Market Share Changes (≥95% & including 100%)		
25	Totals for Classes with Substantial Potential For Change (0% to < 95%)		

Table E.5 Number of Classes Reviewed and Percent Preferred - Year 2

# Classes	Year 2 Results	% Preferred at End of Year 2
54	TOTAL ALL PDL PROGRAMS at end of YEAR 2	93.8%
	Totals for Classes With Only Limited Potential For Market	
	Share Changes (≥95% & including 100%)	
	Totals for Classes with Substantial Potential For Change (0% to< 95%)	

<sup>&</sup>lt;sup>30</sup> Two classes in Year 1 were newly implemented and did not yet have enough data for analysis.

1

Table E.6 Number of Classes Reviewed and Percent Preferred - 1st Half of Year 3

# Classes		% Preferred at End of 1 <sup>st</sup> Half of Year 3
62	TOTAL ALL PDL PROGRAMS at end of 1st Half of YEAR 3	98.7%
	Totals for Classes With Only Limited Potential For Market	
38	Share Changes (≥95% & including 100%)	
	Totals for Classes with Substantial Potential For Change	
24	(0% to< 95%)	

Table E.7 Number of Classes Reviewed and Percent Preferred - 2<sup>nd</sup> Half of Year 3

# Classes	2 <sup>nd</sup> Half of Year 3 Results	% Preferred at End of 2 <sup>nd</sup> Half of Year 3
67	TOTAL ALL PDL PROGRAMS at end of 2 <sup>nd</sup> Half of YEAR 3	95.4%
38	Totals for Classes With Only Limited Potential For Market Share Changes (≥95% & including 100%)	
29	Totals for Classes with Substantial Potential For Change (0% to< 95%)	

Table E.8 Number of Classes Reviewed and Percent Preferred - 1st Half of Year 4

# Classes	1 <sup>st</sup> Half of Year 4 Results	% Preferred at End of 1 <sup>st</sup> Half of Year 4
65	TOTAL ALL PDL PROGRAMS at end of 2 <sup>nd</sup> Half of YEAR 3	95.8%
45	Totals for Classes With Only Limited Potential For Market Share Changes (≥95% & including 100%)	
20	Totals for Classes with Substantial Potential For Change (0% to< 95%)	

#### Preferred Drug Market Share Percentage Shifts

Overall, the **preferred drug market share** shifted from approximately **75.2% to 95.8%** during the Year 1 period, then shifted slightly back toward non-preferred drugs to approximately **93.8%** preferred at the end of Year 2. The preferred drug market share then increased to **98.7%** for the 1<sup>st</sup> half of Year 3, then decreased slightly back to **95.4%** preferred at the end of the second half of Year 3; and, remained steady at approximately **95.8%** preferred through the 1<sup>st</sup> half of Year 4.

Sometimes more expensive PDL drugs were chosen for clinical reasons, based on anticipation of better outcomes. Additionally, some increase in expenditures occurred due to unanticipated rebate or product price changes occurring after the selection of preferred drugs. Expenditures for medications considered preferred per statute – antianxiety, antidepressant, antipsychotic and cross-indicated drugs (commonly referred to as the AAAX drugs) – have increased, but the percentage of total drug expenditures remained constant from Year 1 to Year 2 to the 1<sup>st</sup> half of Year 3 to the 2<sup>nd</sup> half of Year 3 (31% to 30.4% to 30.4% to 30.6% respectively). However in the 1<sup>st</sup> half of Year 4 expenditures for AAAX medications as a percentage of total drug expenditures increased to 38.9%.

# 4.B) Cost to Administer the PDL Program

ACS and OMPP have jointly estimated these administrative program costs as referenced in Table E.3 on page 19. Costs were estimated as about \$1.125 million annually from August 2002 to September 2004. Administrative costs increased beginning in October 2004 with administration of both the PDL and supplemental rebates programs, and were an estimated \$614,000 and \$627,500 for the six months covered in Reports 3 and 4 respectively. These costs were further refined to be an estimated \$675,000 for the six months covered by Report #5.

#### **Discussion and Conclusions**

In response to increases in prescription drug spending and utilization, many public sector pharmacy benefit programs have been developing and implementing a variety of innovative policy solutions for more effective management of pharmacy benefits. One of the methods that several state Medicaid agencies have implemented is the preferred drug list (PDL) program. The concept behind the PDL program is to improve the quality of pharmaceutical care by ensuring that the most clinically appropriate drug is used, while taking into account the relative costs of the available therapeutically equivalent alternatives. PDL programs may be able to address the problems associated with:

- Recipients who rarely see or pay the true costs of their drugs; and therefore have no incentive to choose less expensive, yet equally effective medications.
- Prescribers who lack current knowledge of the true costs of medications being prescribed.

This evaluation demonstrates that a Preferred Drug List program does decrease net drug expenses. The most substantial net savings from federal CMS rebates are realized within the first year of the PDL program when the largest number of recipients shifts from non-preferred drugs to preferred drugs. Furthermore, the market share movement identified through this evaluation suggests that educating prescribers to prescribe and recipients to utilize preferred drugs works. As a result of moving market share to the preferred products, the PDL program produced net savings with both federal and supplemental rebates.

<u>PDL PROGRAM SAVINGS SUMMARY</u>: Over the entire 3.5 year period that the PDL program has been in operation for the state of Indiana, the overall <u>net</u> pharmacy savings is estimated to be \$19.9 million plus \$21.48 million in estimated supplemental rebates for a total estimated savings of \$41.38 million.

Additionally, after following nearly 38,000 recipients in eight therapeutic classes for 3 ½-years post-PDL implementation, no evidence was uncovered to suggest an association between the PDL and negative impacts on the quality of care or the ability for recipients to obtain medications. Specifically, there is no evidence at 12-months, 2-years (25 months), 2 ½ years (31 months), 3 years (37 months), or 3 ½ years (43 months) post-PDL

implementation to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospital services is occurring on a wide, systematic scale.

Although there were documented savings, these savings may have been lessened by three key factors.

- Standard federal rebates Savings resulting from the PDL policy were reduced after considering the impact of lost CMS federal rebates from some preferred drugs. Higher-priced non-preferred drugs sometimes had proportionately higher corresponding CMS federal rebates. When drugs with higher rebates lose market share under a PDL program, rebate amounts can be reduced, and therefore, savings resulting from implementing a PDL program are reduced by the lost rebates.
- Lack of readily available, timely data for decision support Data on relative cost-effectiveness and net cost of drug products, after applying rebates, were not readily available at the beginning of the program. In the past, because each manufacturer applies its rebate after-the-fact, only estimates of the true net cost for drugs can be made until several months after sales are completed. ACS has recently employed modeling tools that now allow for better projections of the cost implications of shifting market share among medications in a PDL therapeutic class.

# • Limits to savings potential:

- o Some PDL classes had a high percentage of pre-implementation usage of the preferred medications offering little opportunity for savings.
- o Some preferred drugs' net costs were higher than the non-preferred drugs (chosen on clinical advantage).
- o Some preferred drugs underwent unexpected price increases.
- Over one-third of the drug budget has automatic preferred status (anti-anxiety drugs, antidepressants, antipsychotics, and cross-indicated drugs, commonly called AAAX drugs).

# **RECOMMENDED ACTIONS:**

Several solutions have the potential to address the reduction of savings from the factors listed above. Savings can best be achieved if a PDL program is combined with methods to increase purchasing power. For example:

• <u>Limit the number of preferred drugs within a given therapeutic class</u> – The amount of savings is directly related to the ability to increase the market share of the more favorably priced medication within a therapeutic class. Moreover, the more preferred products, the less opportunity to move market share and therefore less potential for savings. Assuming that medications are clinically equivalent, the smaller the list of preferred drugs, the more potential to move market share

and obtain supplemental rebates (discussed below). This recommendation should be done in conjunction with the T-committee's re-evaluation of existing criteria and to re-focus the PA review procedure to encourage use of the preferred drug.

• Continue with supplemental rebates – Supplemental rebates for Medicaid pharmacy claims are a form of state action that increases competition in drug pricing. Increased competition helps drive pricing down in a free market where manufacturers are allowed to set prices in accordance to available competition. In a therapeutic class where numerous brand drugs are found to be clinically equal, supplemental rebates encourage competition by allowing manufacturers to submit progressively higher rebate bids. The manufacturer benefits from obtaining greater market share while the State benefits financially in the form of supplemental rebates. Supplemental rebates cannot be obtained separately from the PDL program. Both the PDL and supplemental rebate programs are needed because without a PDL, there would be no basis for negotiating or the State receiving supplemental rebates on drugs chosen as preferred.

Savings have already shown to be further enhanced when supplemental rebates are obtained as part of the PDL program and are calculated into the PDL savings evaluation. Currently, a supplemental rebates program has been phased in. Implementation of supplemental rebates has been very successful. Additional savings after 3.5 years are estimated to be \$ 21.48 million. This is in addition to any savings obtained through the regular PDL program.

- Consider Necessary Statute Changes to Allow for PDL Class Review of "AAAX" Drugs A significant part of the drug spend, that portion having to do with behavioral health drugs ("3A/X-indicated"), remains unmanaged because of those products' preferred status, and that as such the assurance of both clinical and financial controls is foregone. This is a definite fiscal detriment to the Program and the taxpayers who fund the benefit.
- Analyze classes not currently reviewed to determine which classes, if any, may possibly need to be reviewed by the P & T Committee.

In sum, by limiting the number of preferred drugs within a therapeutic class where clinical outcomes are equivalent, choosing less costly preferred drugs, adding supplemental rebates, undertaking necessary statute changes to allow for PDL class review of "AAAX" drugs, and/or broadening the scope of the drug class reviews to encompass the classes not reviewed, the potential for overall savings increases.

# **Summary**

Since the beginning of the first report analyzing the impact of the Indiana PDL program, there has been no evidence found to suggest that access to care is being harmed or that quality of care for recipients has suffered as a result of the PDL program.

<u>PDL PROGRAM SAVINGS SUMMARY</u>: Over the entire 3.5 year period that the PDL program has been in operation for the state of Indiana, the overall <u>net</u> pharmacy savings is estimated to be \$19.9 million plus \$21.48 million in estimated supplemental rebates for a total estimated savings of \$41.38 million.

# **METHODOLOGY**

# CHAPTER 1 IMPACT OF PDL ON HEALTH OUTCOMES OF INDIANA MEDICALD RECIPIENTS BY MEASURING DIRECT MEDICAL COSTS

# Overview and Background

Indiana Senate Enrolled Act No. 228 (SEA 228) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid with prior authorization for drugs not included on the PDL. The concept behind the preferred drug list program is to ensure that Indiana Medicaid recipients receive the most effective prescription drugs available at the best possible price.

Common opposition to PDL programs has been based upon unsubstantiated allegations that negative health consequences may occur due to changes in medication therapy. The Indiana General Assembly required the Indiana Office of Medicaid Policy and Planning (OMPP) to determine if the PDL program served its intent of promoting efficacious and safe drug therapy while minimizing the expenditure to the State.

OMPP requires ACS Government Healthcare Solutions to conduct a study to analyze the Indiana preferred drug list program (PDL) to determine if the PDL results in a negative impact on the health outcomes of Medicaid recipients as well as any cost shifting to other health care providers, laboratory, emergency or hospital services.

This study uses retrospective, paid claims data to evaluate recipient outcomes that may be related to implementation of the PDL program. Any changes in medical utilization or costs for those affected by the PDL program, relative to those not affected, would be *indicators of a possible association* between the PDL program and health outcomes.

#### Methods

#### <u>Data</u>

11/20/2006

The data for this study were derived from the historical paid claims files from the Indiana Medicaid program. Medical data extracts were created and stored on ACS Government Healthcare Solutions data warehouse for the period of March 1, 2002 to March 31, 2006.

#### Inclusion and Exclusion Criteria

## Inclusion Criteria for Therapeutic Classes of Drugs Studied

Therapeutic classes were <u>included</u> in medical analyses for the first study under the following conditions:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, at the time medical data were extracted for the first study in January 2004, recipients taking medications only in therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report #1. The same recipients in these original 8 therapeutic classes (who were still eligible) were subsequently followed-up in the second, third, fourth and fifth reports. Other maintenance therapeutic classes were added to analysis if they met all inclusion criteria.
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation. This criterion was defined as drugs with 95% or less preferred drug use prior to PDL program implementation or prior to the current study period.
- Therapeutic classes approved for use as long-term maintenance therapy for chronic illnesses. This maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or non-preferred drugs for a long, continuous period of time. Long-term maintenance therapy increases the likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

#### **Exclusion Criteria for Therapeutic Classes of Drugs Studied**

Therapeutic classes are <u>excluded</u> from analyses under the following conditions:

- Therapeutic classes in which greater than 95% of recipients used a preferred drug prior to the PDL implementation. These classes were excluded due to an insufficient number of recipients who switched from non-preferred to preferred in order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it

would be impossible to determine if medical expenditures are associated with taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.

• Therapeutic classes with too few recipients taking the medications. The sample size of each therapeutic class must be large enough to obtain statistical significance ( $\alpha = 0.05$  with a medium effect size) with reasonable power (.80).

After applying the criteria to the therapeutic classes for the PDL, recipients receiving medications in the following eight original therapeutic classes were studied for Reports #1 and #2:

- ACE Inhibitors implemented in September 2002
- Proton Pump Inhibitors implemented in September 2002
- Alpha/Beta Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with Calcium Channel Blockers & Loop Diuretics for analyses)
- Calcium Channel Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with October 2002 Alpha/Beta Blocker for analyses)
- Loop Diuretics implemented in October 2002 (Grouped with October 2002 Antihypertensives above for data analyses)
- Platelet Aggregation Inhibitors implemented in October 2002
- Thiazolidinediones implemented in December 2002
- Triptans implemented in December 2002

For Report #2, recipients were selected from the newer therapeutic classes implemented in the 2<sup>nd</sup> year of the PDL program. Sample sizes were evaluated (See Table 1.1). Table 1.1 details the samples sizes of the new therapeutic classes of chronic medication that had the potential to meet medical study inclusion criteria.

The conclusion was made that there was not a large enough sample size to follow the medical or prescription data, and that the new recipients would not add anything meaningful if analyzed. Therefore, Report #2 followed up recipients in the original eight therapeutic classes for a longer medical study period in year 2 of the PDL program.

For Report #3, recipients receiving medications in the original eight therapeutic classes were followed for the 6-month post-period of 26- to 31-months or 2 ½ years post PDL implementation. Additionally, the following therapeutic classes met the inclusion criteria and recipients taking medications in these new classes were evaluated for medical expenditures:

- Antipsoriatics implemented in July 2003
- Miotics and Intraocular Pressure Reducers implemented in July 2003
- Urinary Antispasmotics/ Antiincontinence Agents implemented in May 2003

# Table 1.1. Recipient Summary Data from PDL Changes in Year 2 of the PDL Program

#### **INDIANA MEDICAID**

# Participant Counts Involved with Year 2 PDL Changes Only in 6 Major Therapeutic Classes

Criteria:

- 1. If > 65% days supply + minimum days =>59, then labeled as "Preferred" or "Non-Preferred"
- 2. If < 59 days supply, then labeled as "Insufficient quantity" to determine PDL status
- 3. If < 65% days supply + minimum days =>59, then labeled as "Mixed PDL/Non-PDL Users"

# **ACE Inhibitors**

#### **ACE Inhibitors with CCB**

Participant ID Count	PRE-PDL Period	Post Period	Participant ID Count	PRE-PDL Period	Post Period
49	Insufficient Quan	Insufficient Quan	64	Insufficient Quan	Insufficient Quan
69	Insufficient Quan	PDL	2	Insufficient Quan	Mixed
1	Mixed	Insufficient Quan	63	Insufficient Quan	NPDL
2	Mixed	PDL	1	Mixed	NPDL
1	NPDL	Insufficient Quan	3	NPDL	Insufficient Quan
5	NPDL	PDL	14	NPDL	NPDL
4	PDL	Insufficient Quan	1	PDL	Mixed
1	PDL	Mixed	4	PDL	NPDL
2	PDL	NPDL	3	PDL	PDL
34	PDL	PDL	155	•	•

168

# **HMG CoA Reductase Inhibitors**

# K+ Sparing Diuretics Participant ID

Participant ID		
Count	PRE-PDL Period	Post Period
31	Insufficient Quan	Insufficient Quan
1	Insufficient Quan	Mixed
30	Insufficient Quan	NPDL
4	NPDL	NPDL
4	PDL	Insufficient Quan
2	PDL	Mixed
4	PDL	NPDL
76		

Participant ID		
Count	PRE-PDL Period	Post Period
9	Insufficient Quan	Insufficient Quan
2	Insufficient Quan	Mixed
6	Insufficient Quan	NPDL
3	Insufficient Quan	PDL
20		

.

# **B-Blockers**

Participant ID	PRE	Post	
4	Insufficient Quan	Insufficient Quan	
1	Insufficient Quan	Mixed	
3	Insufficient Quan	NPDL	
2	NPDL	NPDL	
2	PDL	NPDL	

12

For Report #4, recipients receiving medications in the original therapeutic classes listed below were followed for the 6-month post-period of 32- to 37-months or 3 years post PDL implementation. Additionally, one new therapeutic class, Fibric Acids, met the inclusion criteria and recipients taking these medications were evaluated for medical expenditures:

- ACE Inhibitors implemented in September 2002
- Platelet Aggregation Inhibitors implemented in October 2002
- Thiazolidinediones implemented in December 2002
- Miotics and Intraocular Pressure Reducers implemented in July 2003
- Urinary Antispasmotics/ Antiincontinence Agents implemented in May 2003

For Report #5, recipients receiving medications in the original therapeutic classes listed below were followed for the 6-month post-period of 38- to 43-months or 3.5 years post PDL implementation. Ten therapeutic classes met the inclusion criteria and recipients taking these medications were evaluated for medical expenditures:

- ACE Inhibitors
- Calcium Channel Blocker Antihypertensive Drugs
- Angiotensin Receptor Blockers
- Bile Acid Sequestrants
- Fibric Acids
- Platelet Aggregation Inhibitors
- Thiazolidinediones
- SERMs/ Bone Resorption Inhibitors
- Miotics and Intraocular Pressure Reducers
- Urinary Antispasmotics/ Antiincontinence Agents

# **Inclusion Criteria for Recipients**

Recipients were selected for analysis, if they:

- Had a minimum of 6-months of pre- and 6-months of post- prescription and medical claims history available for Study 1, and two years post- prescription and medical data for follow-up Study # 2, 31 months post- prescription and medical data for follow-up Study # 3, 37 months post- prescription and medical data for follow-up Study # 4, and 43 months post- prescription and medical data for follow-up Study #5.
- Were taking drugs in one of the above therapeutic classes and had at least two PDL-related claims in the three-month period prior to PDL implementation. Recipients of PDL medications were further categorized as Preferred Recipients if at least 80 percent of their PDL-related claims were for preferred drugs; they were Non-preferred Recipients if at least 80 percent of their PDL-related claims were for non-preferred drugs. If their usage was mixed not predominantly preferred or non-preferred recipients were excluded from study.

#### **Cohorts**

Recipients were initially categorized by what happened in the three-month period following PDL implementation. Then for follow-up Reports #2 through #5, recipients were categorized by what happened during the follow-up study period.

In each time period studied, there were recipients who: (1) Changed from non-preferred drugs to preferred, (2) Changed from preferred drugs to non-preferred, (3) Did not change from a preferred agent, (4) Did not change from a non-preferred agent, (5) Terminated non-preferred therapy, and (6) Terminated preferred therapy.

The cohorts of particular interest were:

- a. Cohort 1 (Changed Therapy, Persisted on Preferred Therapy): Recipients taking a non-preferred medication for 6-months before implementation of the PDL therapeutic class and switched to a preferred medication after PDL implementation, then persisted with the preferred therapy for up to 3.5 years through March 2006.
- b. Cohort 2 (No Change Group, Persisted on Preferred Therapy): Recipients already taking preferred medication 6-months before and continued taking preferred medication after PDL implementation, and persisted with the preferred therapy for up to 3.5 years through March 2006.
- c. Cohort 3 (No Change Group, Persisted on Non-Preferred Therapy): Recipients already taking a non-preferred medication for 6-months prior to implementation of the PDL therapeutic class and remained on the nonpreferred drug through each of the 6-month study periods for each report.

Additional cohort studied for Report #5 as a post-hoc analysis was:

d. Cohort 4 (Changed Therapy, was taking Preferred and changed back to Non-Preferred Therapy): Recipients taking a preferred medication for 6-months before implementation of the PDL therapeutic class and switched to a non-preferred medication after 2.5 to 3.5 years into preferred therapy.

Recipients with gaps between paid claims in excess of 60 days were excluded from the multivariate analysis of variance (MANOVA) due to the possibility of nonadherence. By definition, recipients with 60-day gaps in paid prescription claims did not utilize Medicaid services for prescriptions and were classified as not having continuous therapy with a drug in one of the therapeutic classes studied. Although patients who may have been non-adherent with their therapy are important, the purpose of this study was to measure the effects of the drugs in the PDL program. Care was given to our recipient study group in order to not bias the study with the effects of non-adherence mixed within.

#### Medical Data Study Period

Analyses of the effects of PDL implementation on medical utilization and costs was limited to certain therapeutic groups where potential changes were most likely to have occurred as a result of PDL implementation. Study period one was 6-months prior to and 6-months after each specific therapeutic class' PDL implementation. The month of implementation was excluded in the medical analyses since most implementations occurred mid-month. Study period two was 12-months post- to two years post-implementation. Study period three was 26 to 31 months post-implementation (10/1/04 to 3/31/05). Study period four was 32 to 37 months post-implementation (4/1/05 to 9/30/05). Study period five was 38 to 43 months post-implementation (10/1/05 to 3/31/06).

#### **Outcome Measures**

Selected outcomes measures studied were expenditures for physician office visits, emergency room services, and laboratory services, as well as number of inpatient hospital admissions and number of inpatient days stayed when hospitalized or institutionalized. Medical outcomes were evaluated 6 months before and for periods of 12, 25, 31, 37 and 43 months after implementation for each of the cohorts or groups of recipients per therapeutic class studied. The initial month of PDL implementation for the associated therapeutic class was assigned a null period in which no measurements were taken.

#### **Outcome Measure Definitions**

Physician office visits were defined by detailed procedure codes associated with outpatient or office services involving physician evaluation and management of patients. Specific procedure codes used to define physician office visits are shown in Table 1.2. Laboratory services were defined by detail procedure codes in the range: 80000-89999 and 95250 (glucose monitoring). Emergency services were defined by locating the emergency physician services using procedure codes 99281-99288, and then rolling up the costs of all detail numbers associated with those emergency services claims.

Table 1.2 Procedure Codes Used to Define Types of Medical Services Studied

Service Types	<b>Detail Procedure Codes</b>	
	99201-99215	
Physician Office or Outpatient Visits	99241-99275	
January and American	99354-99357	
	99361-99380	
Laboratory Services	80000 – 89999	
	95250 – glucose monitoring	
Emergency Physician Services	99281-99288	

Only services related to the disease states treated with the therapeutic class being studied were used in calculating medical expenditures for each service type. This allows a more detailed, narrow scope of expenditures, ensuring that only the expenditures associated with changes in therapy are being included. For example, physician office, lab, or hospital expenditures associated with motor vehicle accidents or broken bones are unrelated to changes in antihypertensive therapy and therefore were not included in measuring expenditure changes between groups.

Inpatient hospital services were measured as a count of each admission date per recipient ID and all expenditures associated with each unique recipient ID per admission date on the inpatient UB-92 claims. Inpatient hospital expenditures were measured only for services related to the disease state associated with the therapeutic class being studied. For example, when analyzing ACE Inhibitors and Antihypertensives, only the DRG and MDC codes for cardiovascular services were measured (see Table 1.3). For thiazolidinediones, expenditures associated with the specific DRG and MDC codes for cardiovascular, endocrine, and kidneys were used.

Table 1.3 DRG Codes Used to Define Medical Services Studied by Disease Type

Medical Services Related to Disease Type:	<b>Detailed Procedure</b>	DRG Codes
	Code	
End-Stage Renal Disease & Dialysis	90918- 90999	302-333
	92950 – 93981 (includes	103-145;
Cardiovascular	extremity arterial &	478,479,514-
	venous studies)	518; 525-527
Endocrine		285-301
Pulmonary	94010 - 94799	N/A
Gastroenterology	91000-91299	N/A
Ophthalmology	92002 - 92499	N/A
Allergy & Clinical Immunology	95004 – 95199	N/A

Table 1.4 MDC Codes Used to Define Medical Services by Therapeutic Classes Studied in Report #5

Therapeutic Class		MDC Code
<u>Antihypertensives</u>		
A4D – ACE Inhibitors		5, 11
A4F – Angiotensin Receptor Blockers		
A9A – Calcium Channel Blocker		
C4N – Thiazolidinediones		5, 7, 10, 11, 19
M9P Platelet Aggregation Inhibitors		5, 16
D7L Bile Acid Sequestrants		5, 7, 23
M4E – Fibric Acids		5, 7, 23
P4L, P4N, P4O – SERMs/ Bone Resorption Inhibitors		0, 8
Q6G – Miotics and Intraocular Pressure Reducers		2
R1A, R1I – Urinary Antispasmotics/ Antiincontinence		11
Agents		

#### **Cost Definition**

To explore the impact of drug use patterns associated with the PDL program on medical costs, Indiana Medicaid claims were partitioned by type of service. The amount actually paid directly by the Indiana Medicaid program minus recipient co-pays and other insurance was used as the Amount Paid for expenditures. We acknowledge that this definition does not capture the full costs of medical expenditures since Medicare is the primary payer for Medicare-covered services and Indiana Medicaid would pay only the balance. However, this study is only measuring differences in paid amounts between two groups. Since we are only interested in payment changes between groups, we contend that amount paid is sufficient because it applies equally to both groups.

#### Report #5 Sample Sizes and Therapeutic Classes Studied

The total sample size studied for Report #5 was 13,554 recipients. Table 1.5 shows the break out of sample sizes by recipient cohorts and by therapeutic class. Cohorts are grouped according to their PDL status prior to implementation and their status during Report period #5. Of 13,554 total recipients, only 364 were affected by the PDL program and switched from non-preferred to preferred medications.

Table 1.5 Sample Sizes and Therapeutic Classes Studied for Report #5

		Value Label	N
Change History	0	No Change: PDL to PDL	11,854
(Cohorts)	1	Change: Non-PDL to PDL	364
	3	No Change: Non-PDL to Non-PDL	1,336
Post-Hoc Cohort Studied	2	Change: PDL Back to Non-PDL	50
Therapeutic Class	A4D	ACE Inhibitors	1,184
	A4F	Angiotensin Receptor Blockers	2,722
	A9A	Calcium Channel Blockers	6,278
	C4N	Thiazolidinediones	548
	D7L	Bile Acid Sequestrants	44
	M4E	Fibric Acids	1,016
	M9P	Platelet Aggregation Inhibitors	328
	P4L,P4N,P4O		1,360
	Q6G		44
	R1A, R1I		80

#### **Method of Analysis**

Comparison of mean medical expenditures was conducted for each therapeutic class by using MANOVA or a multiple comparisons analysis of variance (ANOVA). The issue explored was whether recipients affected by the PDL (i.e., those whose medications were changed from non-preferred to preferred drugs) showed significant

mean differences in expenditures compared to those not affected by the PDL (i.e. those who had no change in their medication). If any changes were observed, post hoc multiple comparisons were conducted to determine which group had greater expenditures. Comparing mean expenditures between groups is one way to estimate if there were any detrimental effects to the health of recipients associated with the PDL program. If detrimental effects occurred from the PDL program drug therapy, patients might require greater medical expenditures from increased physician visits, hospitalizations, and lab monitoring procedures.

#### Results

For Report #5, of the therapeutic classes evaluated, overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences (p-0.181, power=0.717) when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation, or already taking non-preferred prior to and after implementation). In other words, recipients affected by the PDL program were not associated with any statistically significant differences in overall medical expenditures when compared to recipients not affected by the PDL program measured at 43 months after PDL implementation. This finding is consistent with prior Reports #1 through #4 in demonstrating that recipients affected by the PDL program were not associated with any statistically significant differences in overall medical expenditures when compared to recipients not affected by the PDL program measured at 12, 25, 31, 37, and 43 months after PDL implementation.

Analyses were performed on specific medical expenditures and number of inpatient visits in addition to overall medical expenditures for the Report #5 period of 38 to 43 months post PDL implementation. Tables 1.6 and 1.7 gives the MANOVA results in detail.

There were no statistically significant differences between cohorts (recipients affected versus recipients not affected by the PDL program) for physician office visit expenditures (p=0.222, power=0.32), emergency visit expenditures (p=0.475, power=0.18), total medical expenditures (p=0.057, power=0.56), number of inpatient hospitalizations (p=0.358, power=0.23), or number of inpatient days stayed in hospital (p=0.87, power=0.07). There were many zeroes in the paid amounts that skewed the data causing the Levene's test of equality of error variances to be statistically significantly different. However, a natural log transformation did not help rectify the situation. Nevertheless, this MANOVA test seems to be robust enough to capture the correct outcomes.

There was a slight significant difference in laboratory expenditures (p=0.047, power = 0.60) observed for Report #5. When evaluated in post hoc testing, it was determined that the laboratory expenditures were significantly higher for only one therapeutic class – Calcium Channel Blockers. Recipients who were changed from non-preferred to preferred calcium channel blockers had significantly higher lab expenditures during Report #5 study period. Since this is the first study period where this finding was seen, it

is not believed to be a wide-systematic significant difference for all calcium channel blockers.

In sum, when examining specific medical service types at 12, 25, 31, 37 and 43 months after PDL implementation of a therapeutic class, there is no evidence to suggest that specific medical costs (e.g. prescribers, emergency room services or hospital services) are higher on a wide, systematic scale for recipients switched to taking preferred drugs or already taking preferred drugs versus recipients taking non-preferred drugs.

Table 1.6 General Linear Model –MANOVA (Multivariate Tests & Descriptive Statistics)

Multivariate Tests(d)

				Нуро-			Partial		
				thesis			Eta	Noncent.	Observed
Effect		Value	F	df	Error df	Sig.	Squared	Parameter	Power(a)
Intercept	Pillai's Trace	.042	119.32(b)	5.0	13547.0	.000	.042	596.616	1.000
	Wilks' Lambda	.958	119.32(b)	5.0	13547.0	.000	.042	596.616	1.000
	Hotelling's Trace	.044	119.32(b)	5.0	13547.0	.000	.042	596.616	1.000
Change History	Pillai's Trace	.001	1.38	10.0	27096.0	.181	.001	13.827	.717
	Wilks' Lambda	.999	1.38(b)	10.0	27094.0	.181	.001	13.829	.717
	Hotelling's Trace	.001	1.38	10.0	27092.0	.181	.001	13.830	.717

- a Computed using alpha = .05 b Exact statistic
- c The statistic is an upper bound on F that yields a lower bound on the significance level.
- d Design: Intercept+ChangeHistory

11/20/2006

**Descriptive Statistics** 

	Olympia United		011 D. 111	
	Change History	Mean	Std. Deviation	N
Emergency Visit Paid Amt	No Change: PDL to PDL	\$4.80	\$26.11	11,854
	Change: NonPDL to PDL	\$6.47	\$34.47	364
	No Change: NonPDL to NonPDL	\$5.04	\$24.86	1,336
	Total	\$4.87	\$26.25	13,554
Lab Visit Paid Amt	No Change: PDL to PDL	\$15.74	\$46.33	11,854
	Change: NonPDL to PDL	\$21.77	\$52.44	364
	No Change: NonPDL to NonPDL	\$15.17	\$49.18	1,336
	Total	\$15.84	\$46.80	13,554
MD Visit Paid Amt	No Change: PDL to PDL	\$29.65	\$84.32	11,854
	Change: NonPDL to PDL	\$37.44	\$109.84	364
	No Change: NonPDL to NonPDL	\$29.80	\$76.62	1,336
	Total	\$29.88	\$84.39	13,554
Total Medical Paid Amount	No Change: PDL to PDL	\$50.19	\$121.28	11,854
	Change: NonPDL to PDL	\$65.69	\$157.87	364
	No Change: NonPDL to NonPDL	\$50.02	\$117.87	1,336
	Total	\$50.59	\$122.09	13,554
Inpatient Service Count	No Change: PDL to PDL	.11	.41	11,854
	Change: NonPDL to PDL	.10	.39	364
	No Change: NonPDL to NonPDL	.13	.44	1,336
	Total	.11	.41	13,554
Total INPATIENT STAY DAYS	No Change: PDL to PDL	.58	2.69	11,854
	Change: NonPDL to PDL	.62	3.28	364
	No Change: NonPDL to NonPDL	.62	2.70	1,336
	Total	.58	2.71	13,554

Table 1.7 General Linear Model –MANOVA (Tests of Between-Subjects Effects)

Tests of Between-Subjects Effects: For All Therapeutic Classes Combined

	lests of Between	-Subjects Effec	is. Fui i	All Therapeut	iic Ciasses	COIIIL	
							Ob-
		Type III Sum		Mean			served Power
Source	Dependent Variable	of Squares	df	Square	F	Sig.	(a)
Corrected		-		·		.475	.18
Model	Emergency Visit Paid Amt	1026.67(b)	2	513.34	.74		
	Lab Visit Paid Amt	13530.61(b)	2	6765.30	3.09	.046	.60
	MD Visit Paid Amt	21441.35(b)	2	10720.68	1.51	.222	.32
	Total Medical Paid Amount	85277.83(b)	2	42638.92	2.86	.057	.56
	Inpatient Service Count	.35(b)	2	.17	1.03	.358	.23
	Total INPATIENT STAY DAYS	2.05(b)	2	1.02	.14	.870	.07
Intercept	Emergency Visit Paid Amt	74322.05	1	74322.05	107.83	.000	1.00
	Lab Visit Paid Amt	775305.71	1	775305.71	354.14	.000	1.00
	MD Visit Paid Amt	2622532.16	1	2622532.16	368.28	.000	1.00
	Total Medical Paid Amount	7687080.99	1	7687080.99	515.85	.000	1.00
	Inpatient Service Count	32.99	1	32.99	194.56	.000	1.00
	Total INPATIENT STAY DAYS	918.66	1	918.66	124.88	.000	1.00
Change History	Emergency Visit Paid Amt	1026.67	2	513.34	.74	.475	.18
	Lab Visit Paid Amt	13530.61	2	6765.30	3.09	.046	.60
	MD Visit Paid Amt	21441.35	2	10720.68	1.51	.222	.32
	Total Medical Paid Amount	85277.83	2	42638.92	2.86	.057	.56
	Inpatient Service Count	.35	2	.17	1.03	.358	.23
	Total INPATIENT STAY DAYS	2.05	2	1.02	.14	.870	.07
Error	Emergency Visit Paid Amt	9340202.85	13551	689.26			
	Lab Visit Paid Amt	29666934.13	13551	2189.28			
	MD Visit Paid Amt	96497672.99	13551	7121.07			
	Total Medical Paid Amount	201933379.26	13551	14901.73			
	Inpatient Service Count	2297.94	13551	.17			
	Total INPATIENT STAY DAYS	99688.74	13551	7.36			
Total	Emergency Visit Paid Amt	9662642.90	13554				
	Lab Visit Paid Amt	33082736.92	13554				
	MD Visit Paid Amt	108617432.69	13554				
	Total Medical Paid Amount	236707481.49	13554				
	Inpatient Service Count	2476.00	13554				
	Total INPATIENT STAY DAYS	104314.00	13554				
Corrected Total	Emergency Visit Paid Amt	9341229.52	13553				
	Lab Visit Paid Amt	29680464.74	13553				
	MD Visit Paid Amt	96519114.34	13553				
	Total Medical Paid Amount	202018657.10	13553				
	Inpatient Service Count	2298.29	13553				
	Total INPATIENT STAY DAYS	99690.79	13553				

a Computed using alpha = .05

b R Squared = .000 (Adjusted R Squared = .000)

#### Discussion

Of the therapeutic classes evaluated, overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation). It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned to take preferred or non-preferred drugs; therefore, only association or lack of association can be determined. Sample sizes were measured in number of recipients (n=38,724 recipients in Year 1; 23,585 recipients in Year 2; 21,127 recipients in the first half of Year 3; 33,312 recipients in the second half of Year 3; and, 13,554 recipients in the first half of Year 4 [Report #5]).

Report #5 evaluated recipients' medical expenditures of the original therapeutic classes from Reports #1, #2, and #3 that contained large enough recipient sample sizes to evaluate at 43 months post-implementation, plus the additional class that met the inclusion criteria in Report #4 was also included for evaluation of medical expenses. The ten therapeutic classes evaluated for Report #5 were: ACE Inhibitor Antihypertensives, Angiotensin Receptor Blockers (ARB) Antihypertensives, Calcium Channel Blocker Antihypertensives, Bile Acid Sequestrants, Fibric Acids, Platelet Aggregation Inhibitors, Thiazolidinediones, SERM's/Bone Resorption Suppression drugs, Miotics, and Urinary Antispasmotics/Anti-incontinence drugs.

Of all the therapeutic classes evaluated, the evidence does not demonstrate any statistically significant change in overall medical expenditures at 12, 25, 31, 37, and 43 months after PDL implementation. In other words, recipients affected by the PDL program were not associated with a statistically significant difference in overall medical expenditures when compared to recipients not affected by the PDL program.

Analyses were performed on specific medical expenditures in addition to overall medical expenditures. Specific medical service type expenditures analyzed were: prescriber office visits, inpatient hospital admissions, emergency room services, and laboratory procedures. When examining specific medical service types at 12, 25, 31, 37 and 43 months after PDL implementation of a therapeutic class, there is no evidence to suggest that specific medical costs (e.g. other health care providers, lab, emergency room services or hospital services) are higher on a wide, systematic scale for recipients switched to taking preferred drugs or already taking preferred drugs versus recipients taking non-preferred drugs.

#### Conclusion

The Indiana DUR Board and OMPP have demonstrated a commitment to addressing the health care needs of its Medicaid population. OMPP is committed to providing quality health care, while maximizing the financial resources available. The PDL program was implemented to ensure the quality of care and minimize the expenditures to the State of Indiana, while minimizing the impact to recipients and health care providers. As a consequence, OMPP is required to analyze the impact of the PDL program and identify any unintended consequences associated with the PDL program.

For Report #5, in the ten therapeutic drug classes and 13,554 recipients evaluated over the 6-month post-period of 38- to 43-months or 3.5 years post PDL implementation, the evidence does not suggest that recipients affected by the PDL (by requiring a change to a preferred medication) have higher medical costs as a result.

The evidence does not support higher cost shifting to specific medical expenditures, such as increased lab tests, emergency room visits, or physician office visits. Additionally, the evidence does not support higher cost shifting to total medical expenditures. In conclusion, recipients impacted by the PDL program do not demonstrate a statistically significant increase in medical expenditures when compared to recipients not affected by the PDL program.

#### Limitations

Caution must be used in the interpretation of these results. The following limitations should be noted when evaluating the findings of this section.

Retrospective studies, such as this one, are subject to numerous biases. Since it is impractical to operate a Medicaid program like a controlled clinical trial, there may be differences observed in user groups that are not necessarily attributable to the program itself but to other confounding factors that are difficult to control for or are unknown. For this reason, results of retrospective observational studies such as this one are considered associations and not causal.

Furthermore, the type of statistical tests performed can help account for biases known to be a part of the analyses. The between-group variances were significantly different; meaning, one of the assumptions of ANOVA were violated. Yet, ANOVA is known for being a very robust test. A repeated measures analysis was conducted due to its design advantage in reducing the unsystematic variability in the design and so provides greater power to detect effects. Further analyses using the Bonferroni method were performed to verify results. The Bonferroni method has been shown to be extremely robust; it controlled alpha levels and Type 1 error rates the best out of all the univariate techniques. In the first study – which used medical data that was only 6 months post-implementation – Levene's test of equality of error variances was significant for many therapeutic classes and medical service type expenditures, meaning the between-group variances are

significantly different. Levene's test of equality of error variances was most often significant for emergency room services, laboratory, and inpatient hospital services where number of incidences and sample size are low. When sample sizes are low, some recipients in this study may have measurements much different from the average user (outliers) and thus can "skew" the results. The large amount of zero paid amounts for physician office expenditures skewed the data such that even a natural log transformation did not correct the problem. However, the tests used to analyze the data in this study are "robust" enough to limit the effect of "skewed" data.

In the follow-up second study, Levene's test was significant only for physician office expenditures. This phenomenon can be explained by the lag time of receiving medical claims data. Having only 6-months post-implementation data for the first study was a significant problem. After two years, gaps in the medical data for 6-month to 1-year post-implementation had subsided and increased the validity of the medical data. Since prescription claims data are point-of-sale, there is virtually no lag time on prescriptions claims data. However, medical claims data submission is still paper driven in some offices, and is much slower in getting into the database.

It was mentioned in the first Report that steps should be taken in future studies to equalize the variances through data transformation such as taking the square root of the rate of change of all values of the dependent variable, or removing outliers prior to analyses. Data transformation was recommended for future follow-up studies in Report #1. However, in Reports #2 through #5, data transformation did not help equalize the variances. What did finally equalize the variances more than data transformation was analyzing each therapeutic class separately rather than trying to analyze the therapeutic class as a covariate.

There is an apparent selection bias inherent in the cohorts studied. This means that there are systematic differences in the groups studied based on the way the recipients were selected into the study groups. For example, in some therapeutic classes (or disease states), recipients who were already taking the preferred drugs were stabilized and were inherently using less medical resources both pre- and post-PDL implementation than those in the non-preferred groups. It would make sense that users of a medication that a therapeutics committee deemed to be clinically superior would have different health outcomes than those who used a "non-preferred" potentially inferior medication, then switched to the "preferred" medication. Conversely, in some therapeutic classes where the medications were equally effective, recipients switched from a newer, more expensive "non-preferred" medication may not be as sick as a recipient who has been taking an older, less expensive "preferred" medication for a long time.

The medical analyses in this study are based on the paid amounts by the State of Indiana Medicaid Program. Paid amounts (expenditures that the state incurred) are only one measure of costs of providing services. Fluctuations in third party liability (TPL) expenditures and co-pays are not accounted for when using paid amounts. There is also the possibility of missing services performed that have not yet been filed or paid. For

these reasons, this study does not capture trends in the total overall expenditures for medical services but rather the State's liability for the services studied.

The two largest limitations to the first study, low power measures in many of the drug classes studied and the highly skewed medical data were rectified with the second through fifth iteration of this study. Any effects of the program became more evident during subsequent PDL evaluations and we were able to have much more confidence in the statistical results.

The 48-month post-PDL study period is a relatively long-term follow-up. Although, medical illnesses may take longer than 48 months to develop, it seems reasonable to conclude that after a 48-month post period, if any differences in medical expenditures due to the PDL program were going to occur, they would have occurred by now. Further follow-up conducted with longer post-periods will not cause us to gain any additional knowledge or insight.

#### **CHAPTER 2**

## THE EFFECTS OF THE PREFERRED DRUG LIST PROGRAM ON MEDICALD RECIPIENTS' ACCESS TO MEDICATIONS

#### Introduction

Under a PDL program, claims for non-preferred medications cause a denial edit to post on the dispensing pharmacy's point of service response. This edit directs the pharmacist to contact the prescriber. The prescriber may either instruct the dispensing pharmacist to dispense a "preferred medication," call an ACS consulting pharmacist to discuss alternative therapy, or request prior approval from the Indiana Medicaid program or its contractor to use the originally prescribed "non-preferred" medication.

Claim denials may also occur if there is an attempt to refill a prescription too early. The prescriber may discuss any of these events with the reviewing pharmacist to arrive at an appropriate course of action. The possible outcomes of denied claim events are: 1) the new prescription is filled without delay, 2) the new prescription is filled after a delay, or 3) no related or follow-up prescription is prescribed.

Concern has been expressed by some patient advocates, manufacturers, prescribers, patients and others that a Preferred Drug List program may cause some patients harm by either causing a delay in starting on prescribed medications or by potentially "restricting access" to medications. Specifically, if pharmacists cannot contact the prescriber and bring resolution to the denied claims rather quickly, patients may leave the pharmacy with no medication. Some patients will eventually receive medications after a delay; while, other patients may choose not to follow-up later thereby, in essence, terminating therapy previously begun, or never starting the drug therapy.

First, not all delays or therapy terminations associated with a PDL program are undesirable. Delays can occur between the time of the denial and the next fill because the participant attempted to receive an early refill. The physician might not have chosen to call for a prior authorization and simply allowed the therapy to terminate because the prescription was no longer necessary. There might have been no follow up prescription filled because the member was no longer eligible for Medicaid.

Second, some delays seen through the prescription claims data are not actually delays in therapy. The physician may have given the recipient prescription samples. Although a delay in the payment for a claim is quantifiable, it is difficult to truly quantify an actual delay in therapy from claims data. A pharmacist may choose to dispense a small supply of denied medication for a recipient until such time that the prescriber requests a prior authorization for the product.

Nevertheless, although it is desirable to increase the share of "preferred" medications versus "non-preferred" medications, when claims are denied, it is important to enable

participants who need prescribed medications to obtain them while limiting inappropriate use of medications. Therefore, ACS performed an analysis to determine if the implementation of the Indiana State Medicaid Preferred Drug List (PDL) Program had any effect upon medication access for participants.

#### **Report #1 Review**

ACS' claims processing system enabled the identification of denied claims for non-preferred medications in the preferred drug list. Of the 188,508 monthly recipients followed between May and September 2003, only 4,462 (2.36%) experienced a denied pharmacy claim. Most of these recipients went on to receive the medication through a prior authorization approval. Over half of the follow-up claims were processed on the same day that the denial occurred. Therefore, delays in obtaining medications were a problem for only 1.2% of recipients. Of those recipients experiencing a delay, only 1,485 (0.78%) overall and 0.3% recipients receiving prescriptions for antihypertensives experienced a denied claim with no prior approval of a non-preferred medication, and no paid claim for a related medication within 30 days. The percent of eligible participants experiencing an exception event, and not receiving a medication within 30 days of the event, ranged from 0.3% for the antihypertensive classes to at its highest 1.6% in the twelve months after the July 2002 implemented PDL classes.

Further, denials for a given class diminished monthly as providers gained experience with the program. It is impossible to know from pharmacy claims data what portion of these dropped claims were clinically inappropriate to be getting filled anyway, such as duplicate or unnecessary therapies. Overall, the low percentage suggests a minimum impact on PDL users. We do not know how many of the dropped claims were due to medications having no refills left as opposed to being new medications with refills left. While we understand that some dropped claims may have come from medications with no refills, this analysis was not included in the study.

Therapy termination was an expected and potentially desirable outcome for the preferred drug list program. The PDL intervention was helpful in flagging cases of inappropriate therapy or therapy that was due to be discontinued. Therefore, some share of those exception events that were without follow up would be appropriate. Again, it was not possible to assess the degree to which exception events with no follow up medication were desirable or were instead the result of recipients, physicians or pharmacists who failed to follow through with their respective responsibilities.

#### Report #2 Review

Since between 30 to 50% of all patients fail to follow their prescribed therapy<sup>31</sup> once they receive it, non-adherence or lack of persistence with taking medications may be a larger concern. Therefore, Report #2 analysis examined recipients who were non-adherent (as

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<sup>&</sup>lt;sup>31</sup> American Medical Association – Report #2 of the Council on Scientific Affairs, 1998.

evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

#### Report #2 Methods

For the purposes of studying non-adherence, recipients were classified as follows. Recipients were followed from March 2002 to September 2004. The Indiana Medicaid recipients had an overall rate of non-adherence of 26.4%.

Table 2.1. Sample Sizes

		Value Label	N
Persistence	20	No Change, PDL to PDL, Persistent Tx	7,198
	21	Non-PDL to PDL Change, Persistent PDL Therapy	4,259
	30	No Change, Mild Non-Adherence	747
	31	Non-PDL to PDL Change w/ Mild Non-Adherence	400
	90	No Change, PDL to PDL, Severely Not Persistent w/ PDL med	1,820
	91	Non-PDL to PDL change, Severely not persistent with PDL med	1,150

#### Report #2 Results

Results showed that even recipients who were classified as "mildly non-adherent" with their medications (defined as recipients who missed at least 2 prescriptions of 30-day therapy in the past 12 months) were significantly different from recipients who persisted with their therapy. Results also demonstrated that there were no significant differences in whether recipients were previously taking non-preferred and switched to preferred medications or had been on preferred medications all along (see Chapter 3); however, there were significant differences between recipients who were persistent in taking their therapy and those who were non-adherent (see Table 2.2).

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were non-adherent (Table 2.3).

#### Report #2 Conclusions

In conclusion, the results help illustrate that health outcomes for Indiana Medicaid recipients are less likely to be related to whether recipients are taking non-preferred or preferred medications, but rather whether recipients will be adherent with taking any medication, be it preferred or non-preferred.

#### Table 2.2. MANOVA on Adherence

#### Tests of Between-

Source	Dependent	Type III Squares	df	Mean	F	Sig.	Partial Squared	Noncent. Parameter	Obser Power
Jource	MDP	18356458 b	6	30594098	49.5	.00	.01	297.0	1.0
Corrected	ERP	11535275°	6	1922545	31.6	.00	.01	190.0	1.0
	LabP	2846671 <sup>d</sup>	6	474445.	6.1	.00	.00	36.8	.99
	TotalMed	477808395 e	6	79634732	3.8	.00	.00	22.8	.96
Intercept	MDP	137853312	1	137853312	2231.	.00	.12	2231.	1.0
шин	ERPaid	65993909	1	65993909	1087.	.00	.06	1087.	1.0
	LabPaid	83322469	1	83322469	1078.	.00	.06	1078.	1.0
	TotalMed	1483749865	1	1483749865	708.9	.00	.04	708.9	1.0
Thera Class	MDPaid	14229582	1	14229582	23.0	.00	.00	23.0	.99
	ERPaid	1413640	1	1413640	23.2	.00	.00	23.2	.99
	LabPaid	407434.	1	407434.	5.2	.02	.00	5.2	.63
	TotalMed	368184176	1	368184176	17.5	.00	.00	17.5	.98
Persistence	MDPaid	16830785	5	33661571	54.4	.00	.01	272.4	1.0
	ERPaid	10159820	5	2031964	33.4	.00	.01	167.3	1.0
	LabPaid	2552353	5	510470.	6.6	.00	.00	33.0	.99
	TotalMed	153669542	5	30733908	1.4	.19	.00	7.3	.52
Error	MDPaid	961823271	155	617860.					
	ERPaid	94505715	155	60709.					
	LabPaid	120305433	155	77282.					
	TotalMed	32580934090	155	20929488					
Total	MDPaid	1550912887	155						
	ERPaid	122979326	155						
	LabPaid	158727188	155						
	TotalMed	41660053047	155						
Corrected	MDPaid	980179730	155						
	ERPaid	95659242	155						
	LabPaid	120590100	155						
	TotalMed	32628714929	155						

a. Computed using alpha = .05

b.R Squared = .019 (Adjusted R

c.R Squared = .012 (Adjusted R

d.R Squared = .002 (Adjusted R

e.R Squared = .001 (Adjusted R

Table 2.3 Mean Differences between Recipients who fill their medication persistently (Persistent Users) and those who are inconsistent in getting their medications filled (Non-Adherent)

#### Descriptive

	Persisten	Mean	Std. Deviation	N
MDPaid	No Change, PDL to PDL,	\$553.72	\$705.04	719
	Non-PDL to PDL Change, Persistent	\$525.70	\$671.50	425
	No Change, Mild	\$781.73	\$955.10	747
	Non-PDL to PDL Change w/ Mild	\$791.50	\$966.30	400
	No Change, PDL to PDL, Severely Not me	\$768.24	\$1,023.74	182
	Non-PDL to PDL change, Severely not PDL	\$786.50	\$1,011.40	115
	Tota	\$605.36	\$793.35	1557
ERPaid	No Change, PDL to PDL,	\$118.32	\$223.65	719
	Non-PDL to PDL Change, Persistent	\$115.62	\$237.21	425
	No Change, Mild	\$181.85	\$299.40	747
	Non-PDL to PDL Change w/ Mild	\$190.28	\$329.01	400
	No Change, PDL to PDL, Severely Not	\$169.82	\$273.72	182
	med Non-PDL to PDL change, Severely not persistent with PDL med	\$171.75	\$295.80	115
	Total	\$132.44	\$247.84	1557
LabPaid	No Change, PDL to PDL, Persistent Tx	\$149.15	\$253.69	719
	Non-PDL to PDL Change, Persistent PDL Therapy	\$149.80	\$244.65	425
	No Change, Mild Non-Adherence	\$180.18	\$365.93	747
	Non-PDL to PDL Change w/ Mild Non-Adherence	\$180.25	\$286.58	400
	No Change, PDL to PDL, Severely Not Persistent w/med	\$167.62	\$356.61	182
	Non-PDL to PDL change, Severely not persistent with PDL med	\$185.83	\$325.05	115
	Total	\$156.48	\$278.27	1557
TotalMedPaid	No Change, PDL to PDL, Persistent Tx	\$7,490.36	\$14,977.11	719
	Non-PDL to PDL Change, Persistent PDL Therapy	\$7,652.39	\$14,969.60	425
	No Change, Mild Non-Adherence	\$7,410.17	\$11,868.96	747
	NonPDL to PDL Change w/ Mild Non-Adherence	\$6,702.53	\$8,601.26	400
	No Change, PDL to PDL, Severely Not Persistent w/med	\$8,170.22	\$14,749.94	182
	NonPDL to PDL change, Severely not persistent with PDL med	\$7,829.77	\$11,905.69	115
	Total	\$7,615.10	\$14,474.84	1557

#### **Report #3 Review**

For Report #3, the PDL program's impact on users' access to medications after the PDL program had been operating for some length of time was assessed. ACS' claims processing system enabled the identification of denied claims for non-preferred medications in the preferred drug list. Retail pharmacy prescription claims were examined at 26 and 31 months after initial implementation. Since pharmacy claims for recipients residing in nursing homes were many times billed months after the date of service, only outpatient retail pharmacy claims conducted at point-of-sale were analyzed. Of the 203,463 monthly recipients followed for 26 months after the PDL program began, and of the 208,693 monthly recipients followed for 31 months after the initial PDL program began, only 3,288 (1.5%) experienced a denied claim in the two months of October 1, 2004 and March 31, 2005.

A random sample of 1,000 retail pharmacy Medicaid recipients' claims were analyzed during the month of October 2004 after the recipient experienced a denied claim due to a non-PDL prescription claim. Another random sample of 750 were analyzed in the month of March 2005. Of the 1,750 random recipients followed from the initial claim rejection due to a non-PDL prescription claim, only 47 recipients (0.023%) in October 2004 and 28 recipients (0.013%) in March 2005 experienced a denied claim with no paid claim for a related medication within the next 30 days.

It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. Claims data does not allow full explanation for the therapy interruptions. For example, there are many potential reasons other than PDL such as: physician sampling of medications, other 3<sup>rd</sup> party liability, patient adherence, or changes in patient therapy.

The denied claims were primarily antihypertensive medications, especially Angiotensin Receptor Blockers (ARBs) and ACE Inhibitors. Based upon the pattern that ACS observed as developing after the criteria were implemented, it appears that some providers may have been attempting to bypass the intent of the Indiana criteria instituted. For example:

- When eye drop claims denied, a pattern revealed some pharmacy providers resubmitted with an emergency override code and input 3-days as the days supply. This pattern allowed the claim to process and pay; thereby, bypassing the edit criteria.
- When there was a denial for step therapy for ARBs where recipients must have failed an ACE Inhibitor first, a pattern revealed some providers switched the claim from plain ARBs to combination ARBs with HCTZ that had no step therapy criteria. This immediate switch allowed the claim to process and pay; thereby, bypassing the edit criteria.

#### **Report #4 Review**

In the period from April 1, 2005 to September 30, 2005, 198,479 claims denied due to a non-PDL edit for 55,241 recipients. Many of these claims were repeated submissions by the pharmacy of the same drug on the same day.

For Report #4, Medicaid recipients' claims were followed and analyzed during the month of September 2005. This time, analysis focused on two therapeutic classes of maintenance medications – the antihypertensive drugs, ACE Inhibitors, and the antidiabetes drugs, thiazolidinediones. Only 107 recipients experienced a claim rejection due to a non-PDL ACE Inhibitor prescription claim, and no recipients experienced a claim rejection due to a non-PDL thiazolidinedione. Of the 107 recipients who experienced a claim rejection due to non-PDL ACE Inhibitors, only two recipients experienced a denied claim with no paid claim for a related medication within the next 30 days. It is impossible, with such a small sample of two, to conclude whether these two recipients were simply aberrations and no longer needed the antihypertensive medication or whether the two recipients' access to care was really impaired. Both recipients received medications for other problems after experiencing a denied claim for a non-PDL ACE inhibitor.

#### Report #5 Review

Report #5 evaluated the period from October 1, 2005 to March 31, 2006. During this 6-month period, 101,163 claims denied for 33,911 recipients due to a non-PDL edit. This translates into 5,651 (4.3%) of the average monthly users of medications experienced a denied pharmacy claim due to the PDL exception. Many of these claims were repeated submissions by the pharmacy of the same drug on the same day. Meaning, the rate of recipients who were truly denied medication due to a non-PDL edit was significantly lower. Furthermore, not all denied claims result in medications not filled. Additionally, recipients who experience a denied claim may no longer need the medication. For example, a short-term therapy such as an ointment or antibiotic may no longer be needed and thus the recipient may be more likely not to get the medication filled after experiencing a denial.

To determine more accurately the PDL program's impact on users' access to medications, Medicaid recipients' claims were followed during the month of January 2006 for 15 therapeutic classes of maintenance medications. The 15 therapeutic classes of maintenance medications analyzed were: antihypertensive drugs (angiotensin converting enzyme inhibitors [ACE inhibitors], angiotensin receptor blockers [ARBs], calcium channel blockers [CCB], ACE inhibitors with CCB, beta blockers, and alpha & beta blockers); thiazolidinediones; alpha adrenergic blockers; triptans; platelet aggregation inhibitors; miotics/other intraocular pressure reducers; urinary tract antispasmotic/anti-incontinence agents; and antipsoriatics.

Of the 15 therapeutic classes in the month of January 2006, a total of 27,656 unique recipients had paid and denied claims. For January 2006, 27,398 recipients (99.1%) had paid claims and only 258 recipients (0.9%) experienced a denial. Twenty-six of the 258 recipients experienced a denied claim with no subsequent paid claim because they were no longer eligible. Of 232 (0.84% of 27,656) recipients still eligible and who experienced a denied claim, 35 (0.13%) recipients did not have a subsequent paid claim and 197 (0.71%) recipients had a subsequent paid claim. Of the 197 recipients (who had a subsequent paid claim, 163 (83% of 197 and 0.59% of total recipients) received a paid claim within 24 hours to 30 days after the PDL exception denial hit. Many of the 163 recipients who had exceptions with subsequent paid claims were getting early fills of medication; therefore, if recipients received the medication within 30 days of the PDL exception, there should be no break or stoppage in taking therapy due to lack of access to medications. Of the 197 recipients who experienced a PDL exception (denial) and who had a subsequent paid claim, 34 (17% of 197 and 0.12% of total recipients) received a paid claim within 31 to 180 days of the denial.

The 34 (0.12%) recipients who experienced a denial with a subsequent paid claim 31 to 180 days later may have experienced a delay in taking medication. There is also possibility that some of these recipients had samples or other medications at home and therefore didn't request the medication again until they needed it. Of the 35 (0.13%) recipients who did not have a subsequent paid claim, it is impossible to determine how many may have gotten their medications through the Medicare D program and how many may no longer have needed the maintenance medication.

Overall, the initial number of recipients who may have experienced a delay in receiving needed medications (0.78% without a related claim within 30 days of the denial in the first year) suggests a minimum impact on PDL users. Further, denials diminished monthly as providers gained experience with the program as evidenced by the 0.023% at 26 months and 0.013% at 31 months after the program began.

Finally, in January 2006 even with the confusion of Medicare D implementation, the number of Medicaid recipients who may have experienced a delay in receiving medications (0.12% without a related claim within 30 days of the denial and 0.13% without a related Medicaid paid claim for a total of 0.25%) suggests a minimum impact on PDL users.

#### **Conclusions About Access to Care**

Conclusion 1: The proportion of users with an exception event (a denied claim due to PDL program) was low.

In this analysis period, only 4.3% of recipients of drug classes subject to the PDL experienced an exception event.

## Conclusion 2: Recipient ineligibility explains why some exception events did not result in a prescription being filled for a medication in the class or a related class.

Twenty-six of the 258 recipients who experienced a denied claim with no subsequent paid claim were no longer eligible.

## Conclusion 3: Delays in the receipt of medications were in part due to recipients seeking to refill their prescriptions too early.

Many of the 163 recipients who experienced a denial with subsequent paid claims were getting early fills of medication; therefore, if recipients received the medication within 23 to 30 days of the PDL exception, there should be no break in taking therapy due to lack of access to medications.

## Conclusion 4: Relatively few eligible recipients with an exception event had no claims for follow up medication in the same or a related class within 30 days of the event.

For the Report #5 period, only 69 recipients or 0.25% of recipients studied did not have a claim for the same medication or one in a related class within 30 days of the exception. The percent of eligible recipients experiencing an exception event, and not receiving a medication within 30 days of the event, ranged from 0.13% for the antihypertensive classes to 2.1% for the Triptan PDL class.

Of the 69 recipients (0.25%) who did not have a claim within 30 days of the exception, 0.12% did have a subsequent paid claim, but the paid claim was 31 to 180 days after the exception event. Of the 0.13% recipients remaining who did not have a subsequent paid claim at all, it is impossible to determine how many may have gotten their medications through the Medicare D program and how many may no longer have needed the maintenance medication.

Not all delays or therapy terminations associated with a preferred drug list program should be considered detrimental. Claims data does not allow explanation for the therapy interruptions. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate.

Overall, the initial number (0.78% without a related claim within 30 days of the denial in the first year) suggest a minimum impact on PDL users. Further, denials for a given class diminished monthly as providers gained experience with the program as evidenced by the 0.023% at 26 months, 0.013% at 31 months, and 0.13% at 43 months after the program began.

To put this into perspective, the rate of non-preferred claims denials where recipients had no later related claim within the next 30 days is far lower than the 30 to 50% non-adherence rate documented in the literature. Since some of the 0.013% to 0.78% of recipients with therapy terminations associated with the PDL program may have been clinically appropriate, and since between 30 to 50% of all patients fail to follow their prescribed therapy once they receive it, non-adherence or lack of persistence with taking medications seems to be a much larger concern.

## CHAPTER 3 PREFERRED DRUG LIST PROGRAM PRIOR AUTHORIZATIONS

Preferred Drug List (PDL) program prior authorizations (PA's) requested, approved, and denied are listed in Table 3.1 below. In order to give two different perspectives on the PA's requested for non-preferred drugs, both calendar year and federal fiscal year summary figures along with partial year data are listed in Table 3.1.

The percentage of prior authorizations (PA's) for non-preferred drugs that were approved slightly decreased from 99.5% (between August 2002 to December 2002 when the PDL program first began) to its lowest point of 97.0% in calendar year 2003. The percentage of approved PA's for non-preferred drugs increased from it lowest point in calendar year 2003 (97.0%) through calendar year 2004 (97.7%) and continued to increase into calendar year 2005 (98.9%).

The percentage of prior authorizations (PA's) for non-preferred drugs that were denied slightly increased over the life of the PDL Program from 0.5% denied (between August 2002 to December 2002 when the PDL program first began), then peaked at 1.7% denied in calendar year 2004, then decreased slightly to 0.9% denied by calendar year 2005.

**Table 3.1. Preferred Drug List Prior Authorizations** 

Time Period	Average # Utilizers per Month	Total All PA's Requested	Ap- proved	% Ap- proved	# Ap- proved PUPM*	De- nied	% De- nied	# Sus- pended	% Sus- pended
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	204,840	80,950	79,200	97.8%	0.0322	193	0.2%	1,557	1.9%
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	208,995	75,705	73,681	97.3%	0.0294	1,177	1.6%	847	1.1%
Oct 1, 2004 to Mar 31, 2005 (First 6-months of FFY 2005)	205,982	41,052	40,427	98.5%	0.0327	513	1.2%	112	0.3%
Apr 1, 2005 to Sep 30, 2005 (Last 6-months of FFY 2005)	185,932	30,420	30,072	98.9%	0.0270	312	1.0%	36	0.1%
First 6 months - FFY 2006 (Oct 1, 2005 to Mar 31, 2006) 1 <sup>ST</sup> Half of Year 4 – Report #5	129,790	19,073	18,978	99.5%	0.0244	77	0.4%	18	0.1%
Aug 1, 2002 to Dec 31, 2002	200,054	17,866	17,775	99.5%	0.022	91	0.5%	0	0%
Calendar Year 2003	207,593	73,251	71,053	97.0%	0.029	259	0.4%	1,939	2.6%
Calendar Year 2004	204,754	81,440	79,567	97.7%	0.032	1,352	1.7%	521	0.6%
Calendar Year 2005	174,307	60,129	59,487	98.9%	0.028	546	0.9%	96	0.1%

<sup>\*</sup> Per utilizer per month (PUPM)

Detailed data on PDL program prior authorizations by therapeutic class that were requested, approved, and denied by therapeutic category are listed in the following tables: Table 3.2 to Table 3.5 (for calendar year data) and Table 3.6 to Table 3.11 (for federal fiscal year data).

During the calendar year 2003 (1/1/03 to 12/31/03) there were 73,251 PDL program prior authorizations requested. Of the 73,251 PA's requested, 71,053 were approved (97.0%), 259 were denied (0.4%) and 1,939 were suspended (2.6%).

During the calendar year 2004 (1/1/04 to 12/31/04) there were 81,440 PDL program prior authorizations requested. Of the 81,440 PA's requested, 79,567 were approved (97.7%), 1,352 were denied (1.7%) and 521 were suspended (0.2%).

During the calendar year 2005 (1/1/05 to 12/31/05) there were 60,129 PDL program prior authorizations requested. Of the 60,129 PA's requested, 59,487 were approved (98.9%), 546 were denied (0.9%) and 96 were suspended (0.1%).

#### **TABLE 3.2**

# NUMBER OF PRIOR AUTHORIZATIONS ISSUED BETWEEN AUGUST 2002 AND DECEMBER 2002 BY THERAPEUTIC CLASSES WITH PREFERRED DRUG LISTS IN EFFECT AT THE TIME WITH COUNT OF DENIALS

	Count of PAs		
	Between August	Count of	
	and December	Denied	
PDL Therapeutic Class	<u>2002</u>	<u>PAs</u>	% Denied
	1		0.0%
A4D - ACE Inhibitor	594		0.0%
A4D - ACE Inhibitor W/Diuretics	2		0.0%
A4F - Angiotensin Receptor Blockers	1		0.0%
A4F - Angiotensin Receptor Blockers w/Diuretics	5		0.0%
A4K - ACE Inhibitor w/CCB	16		0.0%
A9A - Calcium Channel Blockers	71		0.0%
C4N - Thiazolidenediones	16		0.0%
D4K - Proton Pump Inhibitors	13,289	90	0.7%
H3F - Triptans	29		0.0%
J5D - Beta Agonists	258	1	0.4%
J7A/B/C - ALPHA/BETA Adrenergic Blockers	1,790		0.0%
M4E - Statins	9		0.0%
M9P - Platelet Aggregation Inhibitors	84		0.0%
P5A - Inhaled Glucocorticoids	97		0.0%
R1M - LOOP Diuretics	22		0.0%
Z2A - Non-Sedating Antihistamines	1,491		0.0%
TOTAL	17,775	91	0.5%

#### Table 3.3 Calendar Year 2003 PAs Related to the PDL Program



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 5/14/2004

Client ID: INCAID

From 01/01/2003 To 12/31/2003

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	594	1	
ACEI with CCB	191		
ACEI with Diuretics	30		
Angiotensin Receptor Blockers (ARBs)	3.824	5	2
Antidiabetic Agents	672	1	
Antiemetic - Antivertigo Agents	66		
Antifungal Oral	848	1	
Antifungal Topicals	602		
Antipsoriatics	3		
Antiulcer- H Pyloric Agents	168		
Antiviral Anti-herpetic Agents	148		
Antiviral Influenza Agents	429		
ARBs with Diuretics	243	2	1
Beta Adrenergic Blockers	211		
Bile Acid Sequestrants	146	2	
Brand Name Narcotics	466	1	
Brand NSAIDS	6.493	61	992
Calcium Channel Blockers	284		
Cephalosporins	482		
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	40		
Duragesic	2,315	4	18
Fibric Acids	84		
Fluoroquinolones	402		
Forteo	59	2	
H2 Antagonists	2.464	11	183
Heparin and Related Products	4		
HMG CoA Reductase Inhibitors	631	2	
Imitrex Tablets Month Limit	51		
Inhaled Glucocorticoids	1,026		
Leukocyte Stimulants	18		
Leukotriene Receptor Antagonists	24		
Long Acting Beta Agonists	239	1	
Loop Diuretics	21		
Macrolides	276		1
Miotics - OIPR	94		
Non-Sedating Antihistamines	1,789	4	
Ophthalmic Antibiotics	368		
Opthalmic Mast Cell Stabilizers	89	1	
Oral Antifungals	49	1	
Otic Antibiotics	55		
Oxycodone and Hydrocodone APAP	145	23	12
Oxycodone IR	109	1	4
Oxycontin	797	2	16
Platelet Aggregation Inhibitors	143		
PROPOXYPHENE WITH APAP	24		
Proton Pump Inhibitors	15,632	12	13
SERMS - Bone Resorption Agents	943	3	2

#### Table 3.3 – continued –



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 5/14/2004

From 01/01/2003 To 12/31/2003

Short Acting Beta Agonists	3,049	3	1
Skeletal Muscle Relaxants	945	1	
Smoking Deterrent Agents	73		
Systemic Vitamin A Derivatives	164		
Thiazolidenediones	1,207		3
Triptans	449		
Ultram and Ultracet	1,242	18	137
Urinary Tract Antispasmodics- Antiincontinence	271		
Vaginal Antimicrobials	736	2	
Zithromax Limit - PDLZPAK	112		
Zofran Tablet Limit (10 tablets per Rx)	15		
Sum:	52,054	165	1,385

Table 3.4 Calendar Year 2004 PAs Related to PDL Program

#### Indiana Medicaid - Preferred Drug List Prior Authorizations

 Key: A=Approved D=Denied S=Suspended
 Run Date: 3/31/2005

 Client ID: INCAID

From 01/01/2004 To 12/31/2004

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	1,469	15	1
ACEI with CCB	105	1	0
ACEI with Diuretics	130	1	0
Acne Agents	7	0	0
Actiq	58	40	0
Agents to treat COPD	28	0	0
Alpha Adrenergic Blockers	75	1	0
Alpha- Beta Adrenergic Blockers	1,248	6	10
Angiotensin Receptor Blockers (ARBs)	4,212	26	31
Antidiabetic Agents	535	3	4
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	812	1	1
Antifungal Topicals	555	4	1
Antipsoriatics	11	0	0
	376	2	3
Antiulcer- H Pyloric Agents	442	1	3
Antiviral Anti-herpetic Agents	151	1	0
Antiviral Influenza Agents ARBs with Diuretics	198	0	2
	51	0	0
Benign Prostatic Hypertrophy	170	1	0
Beta Adrenergic Blockers	1,119	1	1
Beta Adrenergics & Corticosteroids	242	1	0
Bile Acid Sequestrants	111	2	0
Bone Formation Stimulating	1.275	132	157
Brand NSAIDS	345	3	0
Calcium Channel Blockers		0	0
Calcium Channel Blockers w/HMG CoA Reductase Inh	197	78	10
Carafate (Sucralfate)	557	7	1
Cephalosporins		599	
Cox-2 Inhibitor	6,655 2	599	86 0
Difflucan 150mg 2 Tablet Limit PDLDIFLUCAN		0	0
Duragesic	308	4	1
Eye Antibiotic- Corticosteroid Combo	307 386	5	1
Eye Antihistamines	977	0	0
Fibric Acids			-
Fluoroquinolones	278	1	0
Forteo	136	12	_
Growth Hormones	298	44	6
H2 Antagonists	4	0	0
Hematinics	12	0	0
Heparin and Related Products	27	0	0
HMG CoA Reductase Inhibitors	857	4	6
Imitrex Stat Dose Month Limit	1	0	0
Imitrex Tablets Month Limit	4	0	0
Inhaled Glucocorticoids	641	2	1
Inspra	3	0	0

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#### Table 3.4 -- continued --



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/31/2005 Client ID: INCAID

From 01/01/2004 To 12/31/2004		Client ID:	INCAID
Ketolides	10	0	0
Lactulose	1	0	0
Leukocyte Stimulants	35	0	0
Leukotriene Receptor Antagonists	3,356	9	10
Long Acting Beta Agonists	176	1	0
Loop Diuretics	97	3	0
Macrolides	169	1	0
Miotics - OIPR	474	1	1
Narcotics	1,348	24	5
Nasal Steroids and Antihistamines	609	3	0
Non-Sedating Antihistamines	6,680	68	25
Ophthalmic Antibiotics	474	1	0
Opthalmic Mast Cell Stabilizers	70	0	1
Oral Antifungals	18	0	0
Other Lipotropics	1	0	0
Otic Antibiotics	350	3	0
Oxycodone and Hydrocodone APAP	10	0	0
Oxycodone IR	2	0	0
Oxycontin	119	0	1
Plan Limits	7,019	49	21
Platelet Aggregation Inhibitors	263	3	7
Prior Authorization	40	1	1
PROPOXYPHENE WITH APAP	1	1	0
Proton Pump Inhibitors	22,895	126	103
SERMS - Bone Resorption Agents	874	2	0
Short Acting Beta Agonists	2,437	8	1
Skeletal Muscle Relaxants	1,538	12	8
Smoking Deterrent Agents	41	0	0
Stadol- NS	5	0	0
Systemic Vitamin A Derivatives	38	0	0
Thiazolidenediones	1,934	18	6
Topical Estrogen Agents	156	3	0
Topical Vitamin A Derivatives	237	2	0
TPL Claim Too Old	332	2	1
TPL Within Filing Limit	28	1	0
Triptans	415	1	2
Ultracet	1	0	0
Ultram and Ultracet	3	0	0
Urinary Tract Antispasmodics- Antiincontinence	442	3	0
Vaginal Antimicrobials	1,396	7	2
Zithromax Limit - PDLZPAK	12	0	0
Zofran Tablet Limit (10 tablets per Rx)	2	0	0
Sum:	79,567	1,352	521

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#### Calendar Year 2005 PAs Related to PDL Program **Table 3.5**

#### **INDIANA MEDICAID Prior Authorization Activity**

Reporting Date: From 01/01/2005 To 12/31/2005

Calendar Year 2005

PA Program for Non-Preferred Drugs

PA Program for Non-Preferred Drugs PA Type by Therapeutic Class	PA Requests Approved		Suspende d PAs
ACE Inhibitors	642	1	3
ACEI with CCB	70	2	0
ACEI with Diuretics	60	0	1
Acne Agents	202	0	0
Actiq	78	6	0
Agents to treat COPD	755	1	0
Alpha Adrenergic Blockers	12	0	0
Alpha- Beta Adrenergic Blockers	2,238	4	5
Angiotensin Receptor Blockers (ARBs)	3,428	4	10
Antidiabetic Agents	520	<u>0</u>	3
Antiemetic - Antivertigo Agents	192 640	0	1
Antifungal Oral Antifungal Topicals	265	2	1
Antipsoriatics	63	0	0
Antiulcer- H Pyloric Agents	299	0	1
Antiviral Anti-herpetic Agents	383	1	0
Antiviral Influenza Agents	109	1	0
ARBs with Diuretics	184	1	0
Benign Prostatic Hypertrophy	278	0	0
Beta Adrenergic Blockers	48	0	0
Beta Adrenergics & Corticosteroids	861	0	2
Bile Acid Sequestrants	208	0	0
Bone Formation Stimulating	209	0	1
Brand NSAIDS	710	256	2
Calcium Channel Blockers	505	0	1
Calcium Channel Blockers w/HMG CoA Reductase Inh	9	0	0
Cephalosporins	294	1	0
Cox-2 Inhibitor	2,866	172	5
Eye Antibiotic- Corticosteroid Combo	244	1	0
Eye Antihistamines	149	1	0
Fibric Acids	338	0	0
Fluoroquinolones	216	0	2
Forteo	195	24	0
H2 Antagonists	53	0	0
Hematinics	3	0	0
Heparin and Related Products	23	0	0
HMG CoA Reductase Inhibitors	137	0	0
Inhaled Glucocorticoids	501	0	1
Inspra	36	0	0
Ketolides	288 31	0	0
Leukocyte Stimulants Leukotriene Receptor Antagonists	1,390	1	1
Long Acting Beta Agonists	105	1	0
Loop Diuretics	31	0	0
Macrolides	165	0	1
Miotics - OIPR	451	0	1
Narcotics	1,347	9	1
Nasal Steroids and Antihistamines	942	2	1
Non-Sedating Antihistamines	5,894	8	8
Ophthalmic Antibiotics	163	0	2
Opthalmic Mast Cell Stabilizers	23	0	0
Other Lipotropics	653	0	0
Otic Antibiotics	87	0	0
Plan Limits	8,412	13	
Platelet Aggregation Inhibitors	132	0	
Proton Pump Inhibitors	15,306	26	20
PPI/NSAID Combination	3	0	
SERMS - Bone Resorption Agents	684	1	1
Short Acting Beta Agonists	884	0	0
Skeletal Muscle Relaxants	1,546	2	2
Smoking Deterrent Agents	7	0	0
Stadol	1	0	0
Systemic Vitamin A Derivatives	6	0	0
Thiazolidenediones	871	1	0
Topical Estrogen Agents	83	0	0
Topical Vitamin A Derivatives	130	0	1
Triptans	192	1	0
Urinary Tract Antispasmodics- Antiincontinence	977	1	1
Vaginal Antimicrobials	660	1	0
Totals	59,487	546	96

#### Table 3.5 -- continued --

#### **INDIANA MEDICAID Prior Authorization Activity**

Reporting Date: From 01/01/2005 To 12/31/2005

#### Calendar Year 2005

#### Regular PA Program

РА Туре	PA Requests Approved	-	Suspende d PAs
34 Day Supply			
(non-maintenance drugs are limited to 34 day supply)	16	0	0
Drug-Drug Severity Level One	3,328	2	0
Early Refill	107,122	104	82
High Dose	90	0	0
Therapeutic Duplication	680	2	2
Sum:	111.236	108	84

#### Miscellaneous PA Program

РА Туре	PA Requests Approved	PA Requests Denied	Suspende d PAs
Brand Medically Necessary	2,544	22	6
Carafate (Sucralfate)	114	124	0
Cytotec	18	5	0
Growth Hormones	338	24	4
Synagis	884	16	0
Respigam	3,916	196	10
Revatio	0	0	0
Sum:	3,898	191	10

PAs Related to PDL Program - Federal Fiscal Year (FFY) 2003 **Table 3.6** 



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended 3/31/2005 Run Date: Client ID: INCAID

From 10/01/2002 To 09/30/2003

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	750	0	1
ACEI with CCB	160	0	0
ACEI with Diuretics	20	0	0
Alpha Adrenergic Blockers	7	0	0
Angiotensin Receptor Blockers (ARBs)	3,238	4	2
Antidiabetic Agents	509	1	0
Antiemetic - Antivertigo Agents	41	0	0
Antifungal Oral	693	1	0
Antifungal Topicals	309	0	0
Antipsoriatics	1	0	0
Antiulcer- H Pyloric Agents	54	0	0
Antiviral Anti-herpetic Agents	24	0	0
Antiviral Influenza Agents	3	0	0
ARBs with Diuretics	191	2	2
Beta Adrenergic Blockers	1,976	0	0
Bile Acid Sequestrants	112	1	0
Brand NSAIDS	5,993	47	708
Calcium Channel Blockers	270	0	0
Carafate (Sucralfate)	223	36	56
Cephalosporins	334	0	0
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	36	0	0
Duragesic	2,040	4	18
Fibric Acids	25	0	0
Fluoroquinolones	318	0	0
Forteo	31	0	0
Growth Hormones	271	0	12
H2 Antagonists	2,770	10	183
Heparin and Related Products	1	0	0
HMG CoA Reductase Inhibitors	511	0	0
Imitrex Stat Dose Month Limit	16	0	0
Imitrex Tablets Month Limit	40	0	0
Inhaled Glucocorticoids	871	0	0
Lactulose	511	5	102
Leukocyte Stimulants	10	0	0
Leukotriene Receptor Antagonists	7	0	0
Long Acting Beta Agonists	202	1	0
Loop Diuretics	26	0	0
Macrolides	242	0	0
Miotics - OIPR	57	0	0
Narcotics	374	0	0
Nasal Steroids and Antihistamines	1	0	0
Non-Sedating Antihistamines	1,979	0	0
Ophthalmic Antibiotics	178	0	0
Opthalmic Mast Cell Stabilizers	31	0	0
Oral Antifungals	12	0	0

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#### Table 3.6 -- continued --



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

A C S		Run Date: Client ID:	3/31/2005 INCAID
From 10/01/2002 To 09/30/2003			
Otic Antibiotics	21	0	0
Oxycodone and Hydrocodone APAP	144	23	12
Oxycodone IR	134	1	4
Oxycontin	674	2	16
Platelet Aggregation Inhibitors	169	0	0
Prior Authorization	36,827	22	283
PROPOXYPHENE WITH APAP	20	0	0
Proton Pump Inhibitors	8,358	10	13
SERMS - Bone Resorption Agents	780	1	2
Short Acting Beta Agonists	2,452	3	1
Skeletal Muscle Relaxants	714	0	0
Smoking Deterrent Agents	66	0	0
Stadol- NS	44	0	3
Systemic Vitamin A Derivatives	84	0	0
Thiazolidenediones	684	0	2
Triptans	369	0	0
Ultracet	14	0	0
Ultram and Ultracet	1,607	18	137
Urinary Tract Antispasmodics- Antiincontinence	209	0	0
Vaginal Antimicrobials	280	1	0
Zithromax Limit - PDLZPAK	72	0	0
Zofran Tablet Limit (10 tablets per Rx)	10	0	0
Sum:	79,200	193	1,557

Table 3.7 PAs Related to PDL Program - Federal Fiscal Year (FFY) 2004

### India

#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended Run Date: 3/2/2005
Client ID: INCAID

From 10/01/2003 To 09/30/2004

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	1,325	16	1
ACEI with CCB	126	1	0
ACEI with Diuretics	104	1	0
Actiq	32	40	0
Alpha Adrenergic Blockers	67	1	0
Alpha- Beta Adrenergic Blockers	931	6	9
Angiotensin Receptor Blockers (ARBs)	3,642	25	28
Antidiabetic Agents	513	2	3
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	768	1	1
Antifungal Topicals	741	4	0
Antipsoriatics	10	0	0
Antiulcer- H Pyloric Agents	414	2	2
Antiviral Anti-herpetic Agents	433	1	2
Antiviral Influenza Agents	546	1	0
ARBs with Diuretics	204	0	1
Benign Prostatic Hypertrophy	18	0	0
Beta Adrenergic Blockers	131	1	0
Beta Adrenergics & Corticosteroids	829	1	1
Bile Acid Sequestrants	182	2	0
Bone Formation Stimulating	73	2	0
Brand NSAIDS	2,375	92	443
Calcium Channel Blockers	351	3	0
Carafate (Sucralfate)	197	82	26
Cephalosporins	553	5	0
Cox-2 Inhibitor	4,687	488	77
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	6	0	0
Duragesic	919	1	0
Eve Antibiotic- Corticosteroid Combo	204	4	1
Eye Antihistamines	242	4	1
Fibric Acids	921	0	0
Fluoroquinolones	295	1	0
Forteo	113	11	0
Growth Hormones	289	32	8
H2 Antagonists	3	1	0
Hematinics	13	0	0
Heparin and Related Products	22	0	0
HMG CoA Reductase Inhibitors	820	6	7
Imitrex Stat Dose Month Limit	6	0	0
Imitrex Tablets Month Limit	15	0	0
Inhaled Glucocorticoids	861	2	1
Lactulose	96	1	26
Leukocyte Stimulants	33	0	0
Leukotriene Receptor Antagonists	2.788	- 8	10
Long Acting Beta Agonists	209	1	0

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Table 3.7 -- continued --



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 3/2/2005  $\mathbf{c}$ Client ID: INCAID From 10/01/2003 To 09/30/2004 Loop Diuretics 92 147 0 Macrolides Miotics - OIPR 356 0 0 Narcotics 1,110 23 3 262 3 0 Nasal Steroids and Antihistamines 4,868 67 Non-Sedating Antihistamines 24 Ophthalmic Antibiotics 592 0 119 1 1 Opthalmic Mast Cell Stabilizers Oral Antifungals 55 1 0 Otic Antibiotics 307 0 Oxycodone and Hydrocodone APAP 50 0 0 Oxycodone IR 0 0 357 Oxycontin 0 5,244 44 17 Plan Limits Platelet Aggregation Inhibitors 223 3 Prior Authorization 113 4 0 PROPOXYPHENE WITH APAP 22.830 119 124 Proton Pump Inhibitors SERMS - Bone Resorption Agents 809 0 2,723 8 Short Acting Beta Agonists 1 1,360 12 Skeletal Muscle Relaxants Smoking Deterrent Agents 43 0 0 0 0 Stadol- NS 116 Systemic Vitamin A Derivatives 0 0 Thiazolidenediones 2,013 14 116 3 0 Topical Estrogen Agents 164 2 0 Topical Vitamin A Derivatives Triptans 447 Ultracet 3 0 1 17 Ultram and Ultracet 0 0 Urinary Tract Antispasmodics- Antiincontinence 371 3 0 1,510 8 2 Vaginal Antimicrobials 0 Zithromax Limit - PDLZPAK 52 0 Zofran Tablet Limit (10 tablets per Rx) 0 0 73,681 Sum: 1,177 847

### Table 3.8 PAs Related to PDL Program - 1<sup>st</sup> half FFY 2005 (Oct 04 to Mar 05)



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

 Key: A=Approved D=Denied S=Suspended
 Run Date: 7/11/2005

 From 10/01/2004 To 03/31/2005
 Client ID: INCAID

Therapeutic Class or Preferred Drug Description	Α	D	S
AGE Inhibitors	624	0	1
ACEI with CCB	43	2	0
A CEI with Diuretics	61	0	2
Acne Agents	70	0	0
Actiq	47	4	0
Agents to treat COPD	244	0	0
Alpha Adrenergic Blockers	20	0	0
Alpha- Beta Adrenergic Blockers	723	0	3
Angiotensin Receptor Blockers (ARBs)	2,052	5	12
Antidiabetic Agents	490	1	2
Antiemetic - Antivertigo Agents	54	<u>'</u>	0
Antifungal Oral	376	0	0
Antifungal Topicals	209	1	1
Antipsoriatics	5	0	<u>'</u>
	150	0	2
Antiulcer- H Pyloric Agents	290	1	1
Antiviral Anti-herpetic Agents			
Antiviral Influenza Agents	36	0	0
ARBs with Diuretics	105	0	1
Benign Prostatic Hypertrophy	57	0	0
Beta Adrenergic Blockers	61	0	0
Beta Adrenergics & Corticosteroids	452	0	1
Bile Acid Sequestrants	150	0	0
Bone Formation Stimulating	157	0	1
Brand NSAIDS	471	160	2
Calcium Channel Blockers	171	0	0
Calcium Channel Blockers w/HMG GoA Reductase Inh	2	0	0
Caratate (Sucraitate)	77	37	0
Cephalosporins	260	3	1
Cox-2 Inhibitor	2,761	197	14
Eye Antibiotic- Corticosteroid Combo	166	0	0
Eye Antihistamines	190	2	0
Fibric Acids	244	0	0
Fluoroquinolones	138	0	1
Forteo	100	13	0
Growth Hormones	153	20	2
H2 Antagonists	5	0	0
Hematinics	6	0	0
Heparin and Related Products	12	0	0
HMG GoA Reductase Inhibitors	226	0	1
Inhaled Glucocorticoids	36	0	0
Inspra	9	0	0
Ketolides	106	0	0
Leukocyte Stimulants	13	0	0
Leukotriene Receptor Antagonists	699	2	1
Long Acting Beta Agonists	26	0	0
Loop Diuretics	29	1	0
		<u> </u>	

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#### Table 3.8 -- continued --



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 7/11/2005
From 10/01/2004 To 03/31/2005 Client ID: INCAID

From 10/01/2004 To 03/31/2005		Cilent ID:	INCAID
Therapeutic Class or Preferred Drug Description	Α	D	S
Macrolides	103	1	0
Miotics-OIPR	240	1	1
Narcotics	636	5	2
Nasal Steroids and Antihistamines	617	1	1
Non-Sedating Antihistamines	3,790	11	б
Ophthalmic Antibiotics	121	0	0
Opthalmic Mast Cell Stabilizers	16	0	0
Other Lipotropics	122	0	0
Otic Antibiotics	97	1	0
Plan Limits	3,921	10	12
Platelet Aggregation Inhibitors	136	0	0
Proton Pump Inhibitors	13,416	25	30
SERMS - Bone Resorption Agents	569	1	1
Short Acting Beta Agonists	676	0	0
Skeletal Muscle Relaxants	616	1	2
Smoking Deterrent Agents	5	0	0
Stadol- NS	2	0	0
Systemic Vitamin A Derivatives	3	0	0
Thiazolidenediones	757	4	1
Topical Estrogen Agents	61	0	0
Topical Vitamin A Derivatives	110	0	0
TPL Glaim Too Old	336	2	1
TPL Within Filing Limit	54	1	0
Triptans	131	0	0
Urinary Tract Antispasmodics- Antiincontinence	261	0	1
Vaginal Antimicrobials	566	0	0
Sum:	40,432	513	107

#### PAs Related to PDL Program - 2<sup>nd</sup> Half FFY 2005 (Apr 05 to Sep 05) **Table 3.9**



Reporting Date: From 04/01/2005 To 09/30/2005

Federal Fiscal Year 2005

Run Date: 5/10/2006 INCAID Client ID:

A = PA Requests Approved D = PA Requests Denied S = Suspended PAs

#### Regular PA Program

PA Type	Α	D	s
34 Day Supply (non-maintenance drugs are limited to 34 day supply)	12		
Drug-Drug Severity Level One	1,241	1	
Early Refill	35,761	34	33
High Dose	30		
Therapeutic Duplication	238	1	1
Sum:	37,282	36	34

#### Miscellaneous PA Program

PA Type	Α	D
Brand Medically Necessary	842	9
Carafate (Sucralfate)	31	39
Cytotec	11	3
Growth Hormones	79	4
Synagis	73	
Sum:	1,036	55

#### -- continued -- PAs Related to PDL Program - 2<sup>nd</sup> Half FFY 2005 **Table 3.9**



#### Prior Authorization Activity

Reporting Date: From 04/01/2005 To 09/30/2005

Run Date: 5/10/2006

Client ID: INCAID

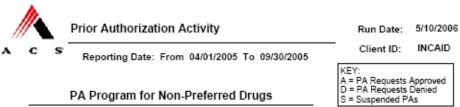
KEY: A = PA Requests Approved D = PA Requests Denied S = Suspended PAs

#### PA Program for Non-Preferred Drugs

PA Type by Therapeutic Class	Α	D	S
ACE Inhibitors	321		
ACEI with CCB	18		
ACEI with Diuretics	27		1
Acne Agents	123		
Actiq	57	2	
Agents to treat COPD	330	1	
Alpha Adrenergic Blockers	10		
Alpha- Beta Adrenergic Blockers	1,129	3	3
Angiotensin Receptor Blockers (ARBs)	2,275	1	4
Antidiabetic Agents	183		1
Antiemetic - Antivertigo Agents	39	1	
Antifungal Oral	415		1
Antifungal Topicals	163	1	1
Antipsoriatics	2		
Antiulcer- H Pyloric Agents	124		
Antiviral Anti-herpetic Agents	220		
Antiviral Influenza Agents	6		
ARBs with Diuretics	110	1	
Benign Prostatic Hypertrophy	30		
Beta Adrenergic Blockers	30		
Beta Adrenergics & Corticosteroids	519		
Bile Acid Sequestrants	102		
Bone Formation Stimulating	90		
Brand NSAIDS	384	139	1
Calcium Channel Blockers	110		1
Calcium Channel Blockers w/HMG CoA Reductase Inh	1		
Carafate (Sucralfate)	31	39	
Cephalosporins	138		
Cox-2 Inhibitor	1,481	78	2
Eye Antibiotic- Corticosteroid Combo	159	1	
Eye Antihistamines	84		
Fibric Acids	198		
Fluoroquinolones	67		
Forteo	94	13	
Growth Hormones	79	4	
H2 Antagonists	4		
Hematinics	2		
Heparin and Related Products	11		
HMG CoA Reductase Inhibitors	69		
Inhaled Glucocorticoids	9		
Inspra	26		
Ketolides	112		
Leukocyte Stimulants	18		

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#### -- continued -- PAs Related to PDL Program - 2<sup>nd</sup> Half FFY 2005 **Table 3.9**



#### PA Program for Non-Preferred Drugs

PA Type by Therapeutic Class	Α	D	S
Leukotriene Receptor Antagonists	651		
Long Acting Beta Agonists	7	1	
Loop Diuretics	9		
Macrolides	57		
Miotics - OIPR	191		
Narcotics	522	4	1
Nasal Steroids and Antihistamines	361	1	
Non-Sedating Antihistamines	3,345	2	1
Ophthalmic Antibiotics	67		1
Opthalmic Mast Cell Stabilizers	14		
Other Lipotropics	431		
Otic Antibiotics	45		
Plan Limits	4,562	7	7
Platelet Aggregation Inhibitors	76		
Proton Pump Inhibitors	7,762	8	10
SERMS - Bone Resorption Agents	210		
Short Acting Beta Agonists	353		
Skeletal Muscle Relaxants	805	2	
Smoking Deterrent Agents	5		
Thiazolidenediones	338	1	
Topical Estrogen Agents	39		
Topical Vitamin A Derivatives	42		
TPL Claim Too Old	1		
TPL Within Filing Limit	24		
Triptans	92		
Urinary Tract Antispasmodics- Antiincontinence	340	1	1
Vaginal Antimicrobials	323	1	
Sum	30,072	312	36

Table 3.10 PAs Related to PDL Program – 1<sup>st</sup> Half FFY 2006 (Oct 05 to Mar 06)

PA Type by PDL Therapeutic Class	Approved	Denied	Suspende
ACE Inhibitors	85	2	1
ACEI with CCB	62	1	0
ACEI with Diuretics	13	0	0
Acne Agents	16	0	0
Agents to treat COPD	289	0	0
Alpha Adrenergic Blockers	0	0	0
Angiotensin Receptor Blockers (ARBs)	969	2	0
Antidiabetic Agents	350	2	0
Antiemetic - Antivertigo Agents	68	0	0
Antifungal Oral	196	0	1
Antifungal Topical	60	0	0
Antipsoriatics	0	0	0
Anti-Ulcer - H Pyloric Agents	97	0	0
Antiviral Anti-herpetic Agent	154	1	0
Antiviral Influenza Agents	6	0	0
ARBs with Diuretics	326	2	0
Benign Prostatic Hypertrophy	19	0	0
Beta and Alpha/Beta Blockers	347	0	0
Beta Adrenergics and Corticosteroids	261	0	0
Bile Acid Sequestrants	67	0	0
Brand NSAIDS	215	25	0
Calcium Channel Blockers	373	0	0
Calcium Channel Blockers w/HMG CoA	10	0	0
Cephalosporins	36	0	0
Cox-2 Inhibitor	806	21	0
Eye Antibiotic- Corticosteroid Combo	0	0	0
Eye Antihistamines	22	0	0
Fibric Acids	391	1	0
Fluoroquinolones	131	0	1
Forteo	62	3	0
Growth Hormones	65	3	0
H2 Antagonists	111	0	0
Hematinics	0	0	0
Heparin and Related Products	9	0	0
HMG CoA Reductase Inhibitors	10	0	0
Inhaled Glucocorticoids	602	0	1
Inspra	10	0	0
Ketolides	98	0	0
Leukocyte Stimulants	14	0	0
Leukotriene Receptor Antagonists	560	0	0
Long Acting Beta Agonists	115	0	0
Loop Diuretics	10	0	0
Macrolides	95	0	1
Miotics- OIPR Narcotics	216	3	2
	1,138		
Nasal Steroids and Antihistamines	416	0	0
Non-Sedating Antihistamines	1,534	0	2
Ophthalmic Antibiotics	75	0	1
Opthalmic Mast Cell Stabilizers	5	0	0
Otic Antibiotics	50	0	1
Other Lipotropics	163	0	0
Plan Limits	1,802	1	1
Platelet Aggregation Inhibitors	31	0	0
Proton Pump Inhibitors	3,969	8	3
PPI/NSAID Combination	4	0	0
SERMS - Bone Resorption Agents	173	0	0
Short Acting Beta Agonists	374	0	0
Skeletal Muscle Relaxants	502	1	1
Smoking Deterrent Agents	2	0	0
Stadol	1	0	0
Systemic Vitamin A Deriv.	7	0	0
Thiazolidenediones	366	0	0
Topical Estrogen Agents	29	0	0
Topical Vitamin A Deriv.	86	0	1
Triptans	84	1	0
	070	^	1
Urinary Tract Antispasmodics - Antiincontinence	676	0	
Urinary Tract Antispasmodics - Antiincontinence Vaginal Antimicrobials	145	0	0

**Table 3.10** -- continued -- PAs Related to PDL Program – 1<sup>st</sup> Half FFY 2006

INDIANA MEDICAID - Regular PA Totals (Oct 05 to Mar 06)

Regular PA Category	Approved	Denied	Suspended
34-Day Supply	12	0	0
Brand Medically Necessary	399	2	0
Carafate (Sucralfate)	68	10	1
Drug-Drug Severity Level One	474	0	5
Early Refill	24,350	14	19
Growth Hormones	65	3	0
High Dose	8	0	0
Respigam	1	0	0
Revatio	15	0	0
Synagis	733	21	5
Therapeutic Duplication	54	0	1
Totals	26,179	50	31

# CHAPTER 4 PHARMACY BENEFIT EXPENDITURE CHANGES (SAVINGS) ASSOCIATED WITH THE PREFERRED DRUG LIST PROGRAM

#### Introduction

This Chapter explores the economic impact of the Preferred Drug List (PDL) program on the pharmacy benefit component of the Indiana State Medicaid Program. The analysis is based on claims paid August 2002 through March 2006.

The "Methods" section describes how pharmacy reimbursement data is integrated with CMS rebate data to estimate the net cost savings for individual PDL classes, taking into account background variability such as price changes, rebate amount changes and seasonal variation in medication use.

The section on "Factors Affecting PDL Program Savings" highlights the effect of CMS federal rebates, preferred drug selection, shifting market share, and utilization on the net cost savings. The dynamic nature of these factors may impact the various therapeutic classes on the Preferred Drug List in different ways. Therefore, in the section on "Performance of Individual Therapeutic Classes Subject to Preferred Drug List," the performance outcomes and some of the factors that affect the outcomes are summarized.

The "Results" section of this chapter reports the overall preferred drug market share changes, estimated expenditure changes, estimated rebate receipt changes, and estimated net savings experienced by the State. It is important to understand that one consequence of shifting utilization to lower priced medications is a potential reduction in CMS rebates. The CMS rebate reduction can be greater than the expenditure savings for a given therapeutic class.

Since clinical considerations are the primary basis for preferred drug selection, scenarios existed where there are no cost savings associated with choosing a particular drug within a therapeutic class. Drug costs are defined as the price paid to the pharmacy less rebates paid to the State by drug manufacturers. The rebates presently received by Indiana Medicaid are those mandated by the federal government through Centers for Medicare and Medicaid Services (CMS) regulations. Changes in rebate amounts arising from market share shifts to other medications within a class affected net savings to the State.

#### Extraction of CMS Rebate Data

Rebate data is available in the ACS Data Warehouse. The CMS data provides a unit rebate amount (URA) for each national drug code (NDC)<sup>32</sup>, the applicable quarter of service, a termination date if needed, and a load date indicating when the record was loaded into the warehouse. Data loads occur quarterly and often include new records updating the URA for earlier quarters of service.

In order to provide a reasonable basis for estimating the ultimate rebate effect of a PDL, the unit rebate amounts were "fixed" when necessary. The basic file consisted of the latest URA available for each quarter of service that was greater than zero. If there were no values greater than zero for an NDC/quarter of service combination<sup>33</sup>, then a value greater than zero for that NDC was borrowed from the nearest adjacent quarter, searching forward and backward. If that method failed to populate the URA cell, then the minimum URA that was greater than zero for that NDC's drug name and quarter of service across all NDCs was used, if one existed. If the value was still zero, then no further effort was made to fix the missing URA value for that NDC/quarter of service combination.

### **Preferred Drug List Savings Calculations**

The method used for estimating PDL savings was based on market share changes for all medications in a therapeutic class covered by the PDL. Market share changes directly affects PDL savings by anticipating *what would have been* spent if no PDL had been implemented *versus what was spent* by having the PDL in place. The method estimated savings for each therapeutic class impacted by the PDL; beginning with the month the therapeutic class was added to the PDL. For each class, month of service, and NDC in the class, the amount paid per claim, the rebate per claim, the net expenditure per claim<sup>34</sup>, and the NDC's market share<sup>35</sup> of total claims were calculated for all the drugs in that class. Multiplying each NDC's market share times its average amount (e.g., paid per claim) and then adding those products for all NDCs in the class was how the overall average per claim amounts for each class was calculated. Those average amounts were the "observed" or "actual" average amount paid per claim, average rebate amount per claim and average net expense per claim.

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NDC refers to the National Drug Code number that uniquely identifies all commercially marketed drug products by their name, strength, package size, delivery route and manufacturer/distributor.
 Just over 5 percent of the NDC/month-of-service combinations required for the Indiana study were

<sup>&</sup>lt;sup>33</sup> Just over 5 percent of the NDC/month-of-service combinations required for the Indiana study were missing URA values. The missing URAs involved about 4 percent of the claims. The above described search process found appropriate URA values for 90 percent of the claims with missing URAs.

Net expenditure per claim was the amount paid per claim less the rebate amount per claim.

<sup>&</sup>lt;sup>35</sup> An NDC's market share was the NDC's percentage share of all claims for the medications in the therapeutic class on the PDL in a given month. If, for example, in a month of service, there were 2,500 claims for an NDC and there were 12,000 claims for all the preferred and nonpreferred medications in the NDC's therapeutic class, then the NDC's market share for that month would be 20.6 percent.

## **Factors Affecting PDL Program Savings**

### **CMS Rebates**

CMS rebates have a significant impact on the financial performance of a PDL program. The "Methods" section of this chapter discusses the extraction and use of CMS unit rebate data to estimate potential rebate receipts for all medications in each affected therapeutic class and the "fixes" performed to the CMS data to infer values when they are either missing for a quarter or were clearly erroneous. The volume of claims involved in the "fixes" is small (see "Methods" discussion). These "fixes" enabled us to make reasonable predictions of the amount billed for drugs in a therapeutic class over time. These fixes are conservative, but still may result in modest underestimation of rebate amounts for some therapeutic classes.

### Supplemental Rebates

Many Medicaid programs solicited rebates directly from participating manufacturers to supplement the CMS rebates for their preferred drugs. Supplemental rebates enhance the CMS rebates and contribute to additional reductions in the net cost of preferred drugs. These rebates are more stable and could limit the variability associated with the fluctuations of the CMS rebates.

### **Preferred Product Selection**

Preferred drug selections are based on initial comparisons of clinical efficacy and safety, followed by a comparison of the relative economic benefits of the medications in each therapeutic class. Due to superior clinical efficacy, there are times when the selected "preferred" drugs were more costly (had higher prices or significantly lower rebates) than the non-preferred drugs in the class so that switching to preferred drugs actually increased the State's net cost. The most costly example of this phenomenon was the August 2002 implementation of the non-sedating or minimally-sedating antihistamines where prices increased and rebates were significantly lower than expected. Another example was the February 2003 implementation of the 'Bone Resorption Suppression' Agents.

As noted in the "Results" section, the preferred drug selection process created some PDL classes containing either all preferred drugs, no preferred drugs, or a mix of preferred drugs representing a very high share of the total number of claims in the class. In those situations, there are generally few opportunities to secure positive savings through the shifting of claims volumes to less costly drugs.

#### **Price Changes and Other Cost Factors**

As indicated above, a Preferred Drug List program is expected to derive savings by shifting prescribing and utilization habits to preferred drugs. Accordingly, the method used to evaluate savings should capture the effects of market changes while controlling for other determinants of cost and cost change. Price and rebate changes affect the ACS

savings estimates only when they changed the relative net expense of drugs that were being switched from non-preferred to preferred in a given month. If there were shifts to or from drugs having a month-to-month change in their net cost relative to other drugs in a class, ACS' method would capture the net cost savings/increases associated with movement to the less expensive or more costly drugs. If the drug mix in a therapeutic class remained stable, then changes in ingredient prices, unit rebate amounts or copayments would not alter the calculated net savings (see "Methods" section).

Inflation, a cause of price change, is an important determinant of pharmacy expenditure growth. The cost-savings methodology used in this report takes into account inflation by estimating net savings based on the average net cost of drugs in a month of service. This methodology does not estimate savings based on any month-to-month change in average expenditure or average rebate which might be due to price inflation or rebate changes generated by manufacturers.

#### Results

Overall, the PDL program significantly increases the utilization of preferred drugs relative to their non-preferred alternatives. In January 2002, 7 months prior to PDL implementation and education about the PDL program, **75.2%** of the claims were for preferred drugs. By July 2002, the month preceding implementation of the first therapeutic classes on PDL, the preferred claim-share had already increased to 79%. By September 2003, the preferred claim-share had increased to almost **95.8%** (See Table 4.1). In September 2004, the preferred claim share had shifted slightly downward to **93.8%**, increased six months later to **98.7%** in March 2005, then shirted slightly downward again to **95.4%** in September 2005, and finally remained fairly steady at **95.8%** preferred drugs dispensed by March 2006.

The change in market share shift toward preferred drugs yielded financial benefits for the State of Indiana in both its first and second year of operation. Supplemental rebates, quantity limits, and step-therapy edits added in the third year significantly boosted financial benefits in the third year of operation.

<u>Year 1</u>. Based on the analysis of the PDL program for 52 classes between August 2002 and August 2003, ACS estimates the total annualized<sup>36</sup> net savings after CMS federal rebate reductions to be approximately **\$8.9 million** (see Tables 4.2 and 4.3). The net pharmacy benefit savings represented 4.4% of total net expenditures projected had the PDL program not been instituted.

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<sup>&</sup>lt;sup>36</sup> Because different classes had been operational for periods ranging from less than 1 month to just over 13 months at the close of the period studied, the observed results were annualized assuming 12 months of operation for all classes. The expected annual payments/rebates/net expenditures were the values that would have been expected had there been no savings/rebate changes over a 1-year period (e.g., observed payments plus the estimated payment savings for the period).

<u>Year 2.</u> Based on the follow-up analysis of the PDL program for 54 classes between October 2003 to September 2004, ACS estimates the net total annualized<sup>37</sup> net savings after CMS rebate reductions to be approximately **\$1.13 million** (see Table 4.4 and 4.5).

TABLE 4.1. Percent Preferred Before and After PDL Implementation – Year 1

IAB		h.1.	Percent Preferred Belo	Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Pre-
Original Imple- menta- tion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates	means lost preferred market share from Year 1)
Aug-02	Oct03, Jun04	Z2A	Z2A - Non-Sedating Antihistamines	24.3%	93.7%	(766,838.25)	94.1%	\$2,263,851	\$12,792,012	0.4%
Sep-02	Oct03, Jul04 Sep03,	A4D	A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	\$63,051	\$4,487,225	-1.0%
	Apr04, Jul04	D4K	D4K - Proton Pump Inhibitors	34.9%	82.4%	6,214,934.91	73.7%	(\$567,862)	\$27,441,018	-8.8%
		J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)	99.8%			
	Mar-04		J7A - ALPHA/BETA Adrenergic Blockers				100.0%	(\$4,493)	\$1,946,456	
Oct-02	Oct-03		J7C - BETA Adrenergic Blockers				99.9%	(\$25,723)	\$4,251,595	2.22
Oct-02			J7B - ALPHA Adrenergic Blockers	04.000	07.00/	(00.470.40)	99.5%	\$1,777	\$196,361	6.3% 0.5%
	-	A9A R1M	A9A - Calcium Channel Blockers R1M - Loop Diuretics	94.0%	97.6% 99.0%	(86,178.42) 6,799.96	98.2% 99.8%	(\$29,766) (\$4,197)	\$10,546,741 \$2,092,918	0.5%
		M9P	M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	(\$13,781)	\$12,192,138	-1.7%
	Oct-03	C4N	C4N - Thiazolidenediones	52.5%	90.1%	713,168.64	98.7%	(\$121,660)	\$10,005,660	8.7%
	Jul-04	A4D	A4D - ACE Inhibitor W/Diuretics	21.8%	90.0%	(2,602.00)	87.8%	\$1,778	\$474,777	-2.3%
	Oct-03	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	95.0%	35,170.70	93.1%	\$8,798	\$1,713,257	-1.9%
	Oct-03	A4K	A4K - Ace Inhibitor w/CCB	95.2%	99.0%	(32,358.44)	100.0%	\$1,984	\$1,379,662	1.0%
	Oct03,Mar04 May04	M4E	M4E - Statins	99.0%	99.6%	(340.978.41)	100.0%	(\$25.315)	\$27,053,472	0.4%
Dec-02	Apr-04	H3F	H3F - Triptans	56.1%	93.4%	200,335.05	92.2%	(\$10,884)	\$2,310,830	-1.2%
	Oct03, Jul04	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	(\$691)	\$1,808,520	-0.1%
	Oct03, Apr04		J5D - Beta Agonists	85.4%	96.0%	1,204,858.72	95.2%	\$296,897	\$9,828,446	-0.8%
		P5A	P5A - Inhaled Glucocorticoids	77.5%	97.7%	100,611.16	93.1%	\$3,897	\$6,609,036	-4.6%
	Apr-04	Q7E/P	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	100.0%	100.0%	(5,285.25)	97.5%	(\$3,718)	\$4,410,943	-2.5%
		Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	\$476,326	\$32,682,425	0.1%
	Mar-04	A4F	A4F - Angiotensin Receptor Blockers	45.7%	88.5%	5,100.34	85.8%	(\$1,146)	\$1,983,049	-2.7%
		WIWXY	V/1V/IX/Y - Cephalosporins	71.7%	99.4%	450,721.61	91.0%		71 101 101	-8.4%
	May-04	WIWXY	W1W - Cephalosporins				99.8%	(\$776)	\$1,121,164	
Jan-03			W1X - 2nd Gen Cephalosporins W1Y - 3rd Gen Cephalosporins				96.9% 76.3%	\$21,949 (\$39,268)	\$605,519 \$2,818,778	-8.3%
		WID	W1D - Macrolides	99.7%	100.0%	(45,111.79)	96.7%	(\$31,765)	\$4,704,570	-3.3%
	Oct03, Sep04		W1Q - Fluoroquinolones	100.0%	100.0%	33,477.28	97.9%	(\$213,557)	\$6,388,476	-2.1%
	Apr-04	W3B	W3B - Antifungals	87.4%	94.7%	408,366.70	92.5%	(\$1,910,968)	\$2,530,547	-2.2%
	Oct03, Jul04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	(\$68,242)	\$3,404,555	-0.6%
Feb-03		M9K	M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	\$1,520,082	\$3,346,150	10.7%
	Jul-04	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	(166,722.99)	93.4%	(\$12,038)	\$7,837,621	-2.2%
	Oct03, Jul04	C4KLM	C4K/L/M - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	(\$102,582)	\$7,096,763	-1.1%
		D7L H3A	D7L - Bile Acid Sequestrants	50.6% 89.3%	71.2% 98.1%	25,373.09	72.2% 98.4%	\$14,737	\$250,538	1.0% 0.3%
May-03	Apr-04	H6H	H3A - Brand Name Narcotics H6H - Skeletal Muscle Relaxants	54.6%	95.6%	279,897.57 381,280.18	98.4%	(\$330,671) (\$73,697)	\$36,088,507 \$4,176,686	-1.9%
		M4E	M4E - Fibric Acids	90.9%	95.4%	(98.801.99)	95.2%	\$43,340	\$2,306,332	-0.2%
	Mar-04	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	(\$44,670)	\$6,166,399	-0.6%
		ЈЗА	J3A - Smoking Cessation	69.8%	85.1%	28,877.34	84.8%	(\$9,744)	\$798,560	-0.4%
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	(1,330.08)				
		L9B	L9B - Topical Vitamin A Derivatives	97.9%	99.3%	(13,515.48)				
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under)				88.8%	\$19,305	\$705,976	
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (over 25)				0.0%	(\$75,700)	\$699,809	-1.7%
	Jul-04	L5F, L1A	L5F - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	(\$7,869)	\$483,398	37.7%
		N1B	N1B - Hematinics	100.0%	93.8%	(164,984.36)	100.0%	\$42,735	\$7,654,848	6.2%
Jul-03		N1C	N1C - Leukocyte Stimulants	80.0%	95.7%	175,583.46	83.9%	(\$18,367)	\$1,252,066	-11.8%
	 Mar04, Apr04,	P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	\$0	0.0%	\$0	\$631,913	0.0%
	Jul04	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	(82,448.16)	79.6%	(\$6,787)	\$2,565,907	4.1%
		Q6I	G6I - Eye Antibiotic/Corticosteroid Combos	14.4%	70.4%	(11,003.97)	76.0%	(\$3,958)	\$91,520	5.6%
	Jul-04	Q6R	Q6R - Eye Antihistamines	99.8%	100.0%	17,824.12	98.9%	(\$3,696)	\$300,017	-1.1%
	Oct-03	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	(6,623.87)	42.4%	(\$366)	\$128,023	1.7%
	Oct03, May04		Q6VV - Ophthalmic Antibiotics	94.3%	83.7%	(18,499.42)	98.2%	(\$101,146)	\$682,031	14.5%
	May-04	Q8VV D4F	Q8F/W - Otic Antibiotics	97.6%	97.9%	(42,935.95) 11,185.20	99.2%	\$33,215	\$942,401 \$21,614	1.3% 0.0%
		Q4F	D4F- Anti-ulcer/H.Pylori Agents Q4F - Vaginal Antimicrobials	8.7%	59.3%	11,185.20 76,684.93	67.1%	\$3,859 (\$403)	\$21,614 \$58,480	7.8%
		Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	(7.353.28)	82.0%	(\$2,350)	\$215,240	-18.0%
	Apr-04	120.00		64.0%	92.6%	49,135.59	83.6%	\$18,217	\$2,150,110	-9.1%
Aug-03	Apr-04 May-04	Q5F	IQ5F - Topical Antifungal Agents							
Aug-03	Apr-04 May-04 Oct-03	Q5F W5A	Q5F - Topical Antifungal Agents W5A - Anti-Herpetic Agents	41.7%	51.6%	247,807.66			¥= :== ::=	
Aug-03	May-04		QSF - Topical Antifungal Agents WSA - Anti-Herpetic Agents WSA - Influenza Agents			247,807.66 0.00				
Aug-03	May-04 Oct-03	W5A	W5A - Anti-Herpetic Agents	41.7%	51.6%		96.0%	(\$33,673)	\$1,621,203	44.4%
Aug-03	May-04 Oct-03	W5A W5A W5A/H6A S2B	WSA - Anti-Herpetic Agents WSA - Influenza Agents WSA - Anti-Herpetic & Influenza Agents S2B - Cox II's	41.7% 0.0% 0.0%	51.6%		0.0%		\$1,621,203 \$11,892,289	
	May-04 Oct-03 Apr-04	W5A W5A W5A/H6A	WSA - Anti-Herpetic Agents WSA - Influenza Agents WSA - Anti-Herpetic & Influenza Agents	41.7% 0.0%	51.6% 0.0%			(\$33,673)	\$1,621,203	44.4%

<sup>&</sup>lt;sup>37</sup> For Report #2 or Year 2 analysis, because different classes had been operational for different periods of time, with quantity limits and other on-going changes during the period studied, the observed results were annualized assuming the second 12 months of operation (actual dates were: Oct03-Sep04) for all classes. Estimates were derived from prescription claims data obtained from OMPP.

TABLE 4.2. Year 1 Estimated Annualized Savings Analysis – Detailed Report by PDL Class

					SHOT WING F	AYMENT AND REB	ATE AWOUNTS					
				Savings/Changes			ld Have Been Over S	ame Twelve Month	its, Rebates and Net s If Program Had Not	Savin	mated Ani gs/Change	es As
			Mor	nths of Full Operat	ion	-	Been I	Operation		Percent	of Expect	ed lota
Implemen-	The second in Class		avment Savings	Rebate Changes	Net Expense	Expected	Expected Annual Payments	Expected Annual	Expected Annual	Payment	Rebate Changes	Net
	Therapeutic Class Z2A - Non-Sedating Antihistamines	\$	796,552	\$ (1,563,391	Savings \$ (766,83	Annual Claims 8) 228,199	,	Rebates \$ 4,542,696	Net Expenses \$ 9,265,366	Savings 5.8%		
	A4D - ACE Inhibitor	\$	239,540	\$ (187,996					\$ 6,221,061	3.0%		_
	D4K - Proton Pump Inhibitors	\$	6,543,025			1				18.8%	-3.6%	_
***10/9/2002	A9A - Calcium Channel Blockers	\$	2,814			8) 219,408	\$ 10,235,570			0.0%	-5.9%	-1.0
10/9/2002	J7A/B/C - ALPHA/BETA Adrenergic B	llockers \$	(95,311)	\$ 33,670	\$ (61,64	1) 267,232	\$ 5,597,942	\$ 922,035	\$ 4,675,907	-1.7%	3.7%	-1.2
++10/9/2002	M9P - Platelet Aggrtegation Inhibitors	\$	(247,175)	\$ 86,614	\$ (160,56	1) 84,572	\$ 8,705,396	\$ 2,442,227	\$ 6,263,170	-2.8%	3.5%	-2.
	R1M - Loop Diuretics	\$	27,028			1				1.0%		_
	A4D - ACE Inhibitor VV/Diuretics		(300)			1				0.0%	-1.6%	-
	A4F - Angiotensin Receptor Blockers		44,731	\$ (9,560				\$ 575,378		2.7%		_
	A4K - Ace Inhibitor w/CCB C4N - Thiazolidenediones	\$	(19,337)			1				-1.6% -13.2%		_
	H3F - Triptans	\$	(1,359,761) 283,488			1			\$ 7,370,642 \$ 2,195,841	9.1%		_
	J5D - Beta Agonists	\$	1,868,973							14.3%		_
	M4E - Statins	\$	(216,561)				\$ 23,951,246			-0.9%	-1.8%	_
	P5A - Inhaled Glucocorticoids	\$	238,929			1				3.8%	-7.4%	_
	Q7E/P - Nasal Anti-histamine/Anti-infle		(31,402)							-0.7%		_
	Q9B - Benign Prostatic Hypertrophy A		(4,157)					\$ 541,518		-0.2%		_
	Z4B - Leukotriene Receptor Antagoni		(18,630)					\$ 1,774,259		-0.3%	-0.1%	_
1/7/2003	A4F - Angiotensin Receptor Blockers	\$	(170,665)	\$ 175,766	\$ 5,10	0 40,028	\$ 1,717,888	\$ 518,278	\$ 1,199,610	-9.9%	33.9%	0.
***1/7/2003	W1D - Macrolides	\$	(42,428)	\$ (2,684	\$ (45,11	2) 140,688	\$ 5,774,135	\$ 1,150,613	\$ 4,623,522	-0.7%	-0.2%	-1.
*1/7/2003	W1Q - Fluoroquinolones	\$	80,312			7 87,305			\$ 3,740,225	1.3%	-2.1%	0.
	W1W/X/Y - Cephalosporins	\$	901,394							17.4%		_
	W3B - Antifungals	\$	720,430							25.5%		_
	H6J - Antiemetic/Antivertigo Agents	\$	91,931			1				3.7%	-2.0%	_
	M9K - Heparin and Related Products		(379,076)			1		\$ 376,183		-13.2%		_
	P4L - SERM's/Bone Resorption Suppri		(54,168)		-					-0.7%	-6.6%	-
	C4K - Antidiabetic Agents	\$	(16,131)							-0.3%		_
	D7L - Bile Acid Sequestrants H3A - Brand Name Narcotics	\$	55,319							14.5%	-38.4% -4.3%	_
	H6H - Skeletal Muscle Relaxants	5	665,416 937,899							13.6%		_
	M4E - Fibric Acids	- I s	(98,679)							-3.8%	0.0%	_
	R1A - Urinary Tract Antispasmodic/A	- 1	681,181	\$ (94,578		1	\$ 7,449,965			9.1%		_
	J3A - Smoking Cessation	\$	37,541	\$ (8,664						5.2%		_
*7/21/2003	L1B - Systemic Vitamin A Derivatives	\$	4,252	\$ (5,583	\$ (1,33	0) 92				10.7%	-14.6%	-76.
*7/21/2003	L5F - Antipsoriatics	\$	20,751	\$ (10,923	\$ 9,82	7 3,452	\$ 410,779	\$ 144,066	\$ 266,714	5.1%	-7.6%	3.
***7/21/2003	L9B - topical Vitamin A Derivitives	\$	17,702	\$ (31,217	\$ (13,51	5) 4,348	\$ 272,090	\$ 95,665	\$ 176,425	6.5%	-32.6%	-7.
*7/21/2003	N1B - Hematinics	\$	(267,654)	\$ 102,670	\$ (164,98	4) 9,412	\$ 5,722,548	\$ 1,310,599	\$ 4,411,949	-4.7%	7.8%	-3.
7/21/2003	N1C - Leukocyte Stimulants	\$	202,904	\$ (27,321	\$ 175,58	3 764	\$ 1,161,282	\$ 249,624	\$ 911,658	17.5%	-10.9%	19
	P4B - Bone Formation Stimulating Age		-	\$ -	\$ -	364	\$ 184,198			0.0%	0.0%	_
	Q6G - Miotics/Other intraocular Press		(2,057)			1				-0.1%		_
	Q6I - Eye Antibiotic/Corticosteroid Cor		73,469	\$ (84,473		1				31.6%		_
	Q6R - Eye Antihistamines	. \$		\$ (2,124						4.5%	-1.3%	_
	Q6U - Ophthalmic Mast Cell Stabilizers Q6W - Ophthalmic Antibiotics	\$ \$	36,673 151,169	\$ (43,296					\$ 82,580 \$ 461,686	24.6% 17.6%		_
	Q8F/W - Otic Antibiotics	, p	151,168 (10,342)			1	· ·		· ·	-0.9%		_
	D4F - Antiulcer/H.Pylori Agents	5	11,621			1				5.2%	-0.5%	_
	Q4F - Vaginal Antimicrobials	-   4	168,470							41.1%		
	Q4K - Topical Estrogen Agents	\$	(347)							-0.1%		
	Q5F - Topical Antifungal Agents	\$	334,832							11.2%		_
	W5A - Anti-Herpetic Agents	\$	210,266							12.8%		_
	W5A - Influenza Agents		-		-							
	S3B - NSAIDS/COX II											
	DL PROGRAMS	\$	12,434,379	\$ (3,524,829	\$ 8,909,56	0 4,936,501	\$ 270,872,141	\$ 70,104,418	\$ 200,767,723	4.59%	-5.03%	4.4
	ses With Only Limited Limited Potential I											١
nare Changes stale for All Cl	s lasses With Substantial Potential For C	hange \$	(136,883) 12,571,262							-0.12% 8.12%	-1.94% -7.26%	_
	iasses With Substantial Potential For C ses With Adverse Savings Potential	nange 5	636,446								-7.20%	
otals for Class	ses With Both Potential For Substantial	Change and										
ith A Potentia	al For Positive Savings	\$		\$ (972,579	\$ 10,962,23	7 1,986,827	\$ 117,467,451	\$ 29,660,934	\$ 87,806,517	∥ 10.16%	-3.28%	12.4
	Classes With Limited Pot			n professed						1		
			isses with no no isses with no pr	n-preferred drugs						-		-
					more than 95 ne	rcent of market sha	are at program start			+		
						ional period to be e						
	Classes Starting With Ne											

# TABLE 4.3. Year 1 Estimated Annualized Savings Analysis Summary

#### **Indiana Medicaid**

**Annualized Estimated Savings Analysis Summary - Year 1** 

Year 1 - Count of Therapeutic Classes		Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)
Classes				(Adjusted Annualized Net
				Savings minus
	Category of Therapeutic Classes	% Pre-ferred	% Preferred	Fed. Rebate)
52	TOTAL ALL PDL PROGRAMS	75.2%	95.8%	\$8,909,550
	Totals for Classes With Only Limited Potential For			
21	Market Share Changes (>95%)			(\$708,829)
6	Classes With all Preferred Drugs (100%)			
	Totals for Classes with Substantial Potential For			
22	Change (<=94%)			\$9,618,379
3	Classes with all NonPreferred Drugs (0%)			

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

**TABLE 4.4. Year 2 Estimated Annualized Savings Analysis Summary** 

#### **Indiana Medicaid**

**Annualized Estimated Savings Analysis Summary - Year 2** 

Year 2 - Count of Therapeutic Classes		Sept/Oct 04 (End Year 2 of PDL Program)	Annualized Net	Annualized Estimated Amount Paid Total Rebates. Contains both
			Savings minus	state and
		% Preferred	Fed. Rebate)	Federal
54	TOTAL ALL PDL PROGRAMS	93.8%	\$1,128,929	\$298,601,311
	Totals for Classes With Only Limited Potential			
22	For Market Share Changes (>95%)		\$1,036,467	\$195,966,447
6	Classes With all Preferred Drugs (100%)		\$478,337	\$71,857,023
	Totals for Classes with Substantial Potential For			
21	Change (<=94%)		(\$199,404)	\$298,601,311
5	Classes with all NonPreferred Drugs (0%)		\$127,850	\$13,245,624

TABLE 4.5. Year 2 Estimated Annualized Savings – Detailed by PDL Class

				Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Adjusted Annualized Net Savings Over 1st 12 Months (1st Yr of PDL)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total	% Pre- ferred Change from Year 1 to Year 2
Original Imple- menta-	2nd Year Change	Ther	DREEFERDED DRUGG	% Pre-	Ili Droforrod	(Adjusted Annualized Net Savings minus Fed. Rebate)	% Droforrod	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates	(negative means lost preferred market share
tion Date Aug-02	Date Oct03, Jun04	Z2A	PREFERRED DRUGS  Z2A - Non-Sedating Antihistamines	ferred 24.3%	% Preferred 93.7%	(766,838.25)	% Preferred 94.1%	\$2,263,851	\$12,792,012	from Year 1) 0.4%
Aug-02	Oct03, Jul04	A4D	A4D - ACE Inhibitor	33.1%	98.5%	51,543.55	97.5%	\$63,051	\$4,487,225	-1.0%
Sep-02	Sep03,	- T	ATD - AGE III IIIDIGI	33.170	30.370	51,545.55	31.370	\$00,001		
	Apr04, Jul04	D4K	D4K - Proton Pump Inhibitors	34.9%	82.4%	6,214,934.91	73.7%	(\$567,862)	\$27,441,018	-8.8%
		J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	(61,640.62)			#4 04C 45C	
	Mar-04 Oct-03		J7A - ALPHA/BETA Adrenergic Blockers J7C - BETA Adrenergic Blockers				100.0% 99.9%	(\$4,493) (\$25,723)	\$1,946,456 \$4,251,595	
Oct-02			J7B - ALPHA Adrenergic Blockers				99.5%	\$1,777	\$196,361	6.3%
		A9A	A9A - Calcium Channel Blockers	94.0%	97.6%	(86,178.42)	98.2%	(\$29,766)	\$10,546,741	0.5%
		R1M	R1M - Loop Diuretics	93.1%	99.0%	6,799.96	99.8%	(\$4,197)	\$2,092,918	0.8%
		мэр	M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	(160,561.02)	98.4%	(\$13,781)	\$12,192,138	-1.7%
	Oct-03	C4N	C4N - Thiazolidenediones	52.5%	90.1%	713,168.64	98.7%	(\$121,660)	\$10,005,660	8.7%
	Jul-04	A4D	A4D - ACE Inhibitor VV/Diuretics	21.8%	90.0%	(2,602.00)	87.8%	\$1,778	\$474,777	-2.3%
	Oct-03 Oct-03	A4F A4K	A4F - Angiotensin Receptor Blockers w/Diuretics A4K - Ace Inhibitor w/CCB	50.7% 95.2%	95.0% 99.0%	35,170.70 (32,358.44)	93.1% 100.0%	\$8,798 \$1,984	\$1,713,257 \$1,379,662	-1.9% 1.0%
	Oct03,Mar04	1-3713	PART - PAGE INTERNIOR MACCO	33.276	33.0 %	(02,000,44)	100.076	ψ1,304	200,000 د اله	
Dec-02	May04	M4E	M4E - Statins	99.0%	99.6%	(340,978.41)	100.0%	(\$25,315)	\$27,053,472	0.4%
D6C-02	Apr-04	H3F	H3F - Triptans	56.1%	93.4%	200,335.05	92.2%	(\$10,884)	\$2,310,830	-1.2%
	Oct03, Jul04	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	(4,546.86)	98.8%	(\$691)	\$1,808,520	-0.1%
	Oct03, Apr04	J5D P5A	J5D - Beta Agonists	85.4%	96.0%	1,204,858.72	95.2%	\$296,897	\$9,828,446 \$6,609,036	-0.8% -4.6%
	 Apr-04	Q7E/P	P5A - Inhaled Glucocorticoids  Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	77.5% 100.0%	97.7%	100,611.16 (5,285.25)	93.1% 97.5%	\$3,897 (\$3,718)	\$4,410,943	-4.6%
		Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	(20,573.18)	100.0%	\$476,326	\$32,682,425	0.1%
	Mar-04	A4F	A4F - Angiotensin Receptor Blockers	45.7%	88.5%	5,100.34	85.8%	(\$1,146)	\$1,983,049	-2.7%
			W1VV/X/Y - Cephalosporins	71.7%	99.4%	450,721.61		1		
	May-04	WIWXY	W1W - Cephalosporins				99.8%	(\$776)	\$1,121,164	
Jan-03	may-01		W1X - 2nd Gen Cephalosporins				96.9%	\$21,949	\$605,519	
			W1Y - 3rd Gen Cephalosporins				76.3%	(\$39,268)	\$2,818,778	-8.3%
	 0-400 C-+04	W1D W1Q	VMD - Macrolides	99.7%	100.0%	(45,111.79) 33,477.28	96.7% 97.9%	(\$31,765)	\$4,704,570 \$6,388,476	-3.3% -2.1%
	Oct03, Sep04 Apr-04	W3B	W1Q - Fluoroquinolones W3B - Antifungals	87.4%	94.7%	408,366.70	92.5%	(\$213,557) (\$1,910,968)	\$2,530,547	-2.1%
	Oct03, Jul04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	70,323.08	98.4%	(\$68,242)	\$3,404,555	-0.6%
Feb-03		мэк	M9K - Heparin and Related Products	92.3%	89.0%	(316,946.25)	99.8%	\$1,520,082	\$3,346,150	10.7%
	Jul-04	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	(166,722.99)	93.4%	(\$12,038)	\$7,837,621	-2.2%
	Oct03, Jul04	C4KLM	C4K/L/M - Antidiabetic Agents	99.1%	99.9%	(18,101.69)	98.8%	(\$102,582)	\$7,096,763	-1.1%
		D7L	D7L - Bile Acid Sequestrants	50.6%	71.2%	25,373.09	72.2%	\$14,737	\$250,538	1.0%
May-03	Apr-04	H3A H6H	H3A - Brand Name Narcotics	89.3%	98.1%	279,897.57	98.4%	(\$330,671)	\$36,088,507	0.3% -1.9%
		M4E	H6H - Skeletal Muscle Relaxants M4E - Fibric Acids	54.6% 90.9%	95.6% 95.4%	381,280.18 (98,801.99)	93.7% 95.2%	(\$73,697) \$43,340	\$4,176,686 \$2,306,332	-0.2%
	Mar-04	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	586,603.33	97.7%	(\$44,670)	\$6,166,399	-0.6%
		ЈЗА	J3A - Smoking Cessation	69.8%	85.1%	28,877.34	84.8%	(\$9,744)	\$798,560	-0.4%
	Oct03, Jul04	L1B	L1B - Systemic Vit A Derivatives	79.0%	81.8%	(1,330.08)				
		L9B	L9B - Topical Vitamin A Derivatives	97.9%	99.3%	(13,515.48)				
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under)				88.8%	\$19,305	\$705,976	
		L1B/5H/9B	L1B/L5H/L9B - Acne Agents (over 25)				0.0%	(\$75,700)	\$699,809	-1.7%
	Jul-04	L5F, L1A	L5F - Antipsoriatics	55.1%	62.3%	9,827.40	100.0%	(\$7,869)	\$483,398	37.7%
		N1B	N1B - Hematinics	100.0%	93.8%	(164,984.36)	100.0%	\$42,735	\$7,654,848	6.2%
Jul-03		N1C P4B	N1C - Leukocyte Stimulants P4B - Bone Formation Stimulating Agents	80.0% 0.0%	95.7%	175,583.46 \$0	83.9% 0.0%	(\$18,367) \$0	\$1,252,066 \$631,913	-11.8% 0.0%
	 Mar04, Apr04,	. 70	, 45 - Sone Formation Stimulating Agents	3.076	3.0 %	ΦU	3.076	ΦU	ψυυ-1313	3.0 /6
	Jul04	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	(82,448.16)	79.6%	(\$6,787)	\$2,565,907	4.1%
		Q6I	Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	70.4%	(11,003.97)	76.0%	(\$3,958)	\$91,520	5.6%
	Jul-04	Q6R	Q6R - Eye Antihistamines	99.8%	100.0%	17,824.12	98.9%	(\$3,696)	\$300,017	-1.1%
	Oct-03 Oct03, May04	Q6U Q6W	Q6U - Ophthalmic Mast Cell Stabilizers  Q6W - Ophthalmic Antibiotics	20.7% 94.3%	40.7% 83.7%	(6,623.87) (18,499.42)	42.4% 98.2%	(\$366) (\$101,146)	\$128,023 \$682,031	1.7% 14.5%
	May-04	Q8W	Q8FAV - Otic Antibiotics	97.6%	97.9%	(42,935.95)	99.2%	\$33,215	\$942,401	1.3%
		D4F	D4F- Anti-ulcer/H.Pylori Agents	21.20	21.2.70	11,185.20	0.0%	\$3,859	\$21,614	0.0%
		Q4F	Q4F - Vaginal Antimicrobials	8.7%	59.3%	76,684.93	67.1%	(\$403)	\$58,480	7.8%
	Apr-04	Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	(7,353.26)	82.0%	(\$2,350)	\$215,240	-18.0%
Aug-03	May-04	Q5F	Q5F - Topical Antifungal Agents	64.0%	92.6%	49,135.59	83.6%	\$18,217	\$2,150,110	-9.1%
	Oct-03	W5A	W5A - Anti-Herpetic Agents	41.7%	51.6%	247,807.66				
	Apr-04	W5A	W5A - Influenza Agents	0.0%	0.0%	0.00	06.004	(800.070)	£1 £24 202	44.40/
Son C3	Jul-04	W5A/H6A S2B	WSA - Anti-Herpetic & Influenza Agents	0.00	0.0%		96.0%	(\$33,673) \$400,604	\$1,621,203 \$11,892,289	44.4% 0.0%
Sep-03 May-04	Jul-04 May-04	R1H	S2B - Cox II's  R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone	0.0% N/A	0.0% N/A		100.0%	\$199,691 (\$5,031)	\$11,892,289	0.0%
	may-u4									
Total		52	TOTAL ALL PDL PROGRAMS	75.2%	95.8%	\$8,909,550	93.8%	\$1,128,929	\$298,601,311	1.1%
			Totals for Classes With Only Limited Potential For Market Share Changes (>95%)			(\$708,829)		\$1,159,285	\$209,868,834	
			Totals for Classes with Substantial Potential For Change (<94%)			\$9,618,379		\$1,128,929	\$298,601,311	

<u>1st</u> <u>Half Year 3</u>. Based on the analysis of the PDL program for 62 classes between October 1, 2004 and March 31, 2005, ACS estimates the **total 6-month** <sup>38</sup> **net savings after CMS federal rebate reductions to be approximately \$1.8 million** (see Tables 4.6 and 4.7).

**TABLE 4.6. 1st Half Year 3 Estimated Annualized Savings Analysis Summary** 

Indiana Medicaid
Annualized Estimated Savings Analysis Summary - Year 2.5

Annaanzee				
_			Adjusted	
		Sept/Oct 04	Annualized Net	Annualized
		(End Year	Savings Over 26-	Estimated
		2.5 of PDL	31 Months Post-	Amount Paid
Year 2.5 -		Program)	PDL (2.5 Yr of	Total (Year 2.5)
Count of	Category of Therapeutic Classes		PDL)	
Therapeutic	Outogory of Therapeutic Glasses			
Classes			/Adiusted	Prior to Rebates.
			(Adjusted	
			Annualized Net	Contains both
			Savings minus	state and
		% Preferred		
62	TOTAL ALL PDL PROGRAMS	% Preferred 98.7%	Savings minus	state and
62			Savings minus Fed. Rebate)	state and Federal portion.
62	Totals for Classes With Only Limited Potential		Savings minus Fed. Rebate)	state and Federal portion.
62 28	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%)		Savings minus Fed. Rebate)	state and Federal portion.
	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%) Classes With all Preferred Drugs (100%)		Savings minus Fed. Rebate)	state and Federal portion. \$144,999,032
28	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%)	98.7%	Savings minus Fed. Rebate)	state and Federal portion. \$144,999,032
28	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%) Classes With all Preferred Drugs (100%)	98.7%	Savings minus Fed. Rebate)	state and Federal portion. \$144,999,032

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

An additional estimated \$ 6.81 million in savings began to be realized from October 1, 2004 to March 31, 2005 in supplemental rebates.

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<sup>&</sup>lt;sup>38</sup> For Report #3 or 1<sup>st</sup> half of Year 3 analysis, because different classes had been operational for different periods of time, and because new quantity limits and other on-going changes occurring during the period studied, the observed results are estimated 6-month figures according to months 26 – 31 of operation (Actual dates were: Oct 1, 2004-Mar 31, 2005) for all classes. Estimates were derived from prescription claims data obtained from OMPP.

TABLE 4.7. 1st half Year 3 Estimated Savings & Market Share by PDL Class

			Indiana Medicaid PDL Program Evalu						
		Percen	t Preferred Before & After PDL In	nplemer	ntation				
				Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Sept/Oct 04 (End Year 2 of PDL Program)	Mar 05 (End Year 2.5 of PDL Program)	6-month Amount Paid Total (Year 2 to 2.5)	Adjusted 6 month Net Savings Over 26-31 Months Post PDL (2 to 2. Yr of PDL)
Original Imple- menta- tion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Pre-ferred	% Preferred	% Pre- ferred	Prior to Rebates	Annualized Net Savings minus Fed.& Supp. Rebate)
Aug-02	Oct03, Jun04 Oct03, Jun04	Z2A Z2A	Z2A - Non-Sedating Antihistamines (RX) Z2A - Non-Sedating Antihistamines (OTC)	24.3%	93.7%	94.1%	95.0% 100.0%	\$2,964,955 \$879,547	\$117,245 (\$437,203
Aug-02	Oct03, Jul04	A4D	A4D - ACE Inhibitor	33.1%	98.5%	97.5%	99.0%	\$2,047,479	\$263,053
Sep-02	Sep03, Apr04, Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (RX)	34.9%	82.4%	73.7%	82.9%	\$12,479,925	\$2,921
·	Sep03, Apr04,						100.0%	\$302,514	(\$156,019
	Jul04, Dec04	J7ABC	D4K - Proton Pump Inhibitors (OTC)  J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	99.8%			
	Mar03, Mar05 Oct-03		J7A - ALPHA/BETA Adrenergic Blockers J7C - BETA Adrenergic Blockers			100.0% 99.9%	100.0%	\$1,220,547 \$2,393,184	\$28,159 \$41,622
Oct-02			J7B - ALPHA Adrenergic Blockers			99.5%	99.7%	\$93,226	\$9,299
	Oct-02 Oct-02	A9A R1M	A9A - Calcium Channel Blockers R1M - Loop Diuretics	94.0%	97.6% 99.0%	98.2% 99.8%	97.7% 99.9%	\$5,292,286 \$1,008,530	\$145,418 \$54,246
	Oct-02, Dec-04	M9P	MSP - Platelet Aggregation Inhibitors	90.1%	100.0%	98.4%	89.9% 100.0%	\$6,371,035	(\$4,216
	Oct-03, Dec-04 Jul-04, Oct-04	C4N A4D	C4N - Thiazolidenediones A4D - ACE Inhibitor VV/Diuretics	52.5% 21.8%	90.1% 90.0%	98.7% 87.8%	99.8%	\$4,804,426 \$226,028	\$60,985 \$24,745
	Oct-03 Oct-03	A4F A4K	A4F - Angiotensin Receptor Blockers w/Diuretics A4K - Ace Inhibitor w/CCB	50.7% 95.2%	95.0% 99.0%	93.1% 100.0%	91.9% 100.0%	\$943,226 \$816,181	\$19,974 (\$9,876
	Oct03,Mar04,								
	May04, Oct04 Apr-04, Oct-04	M4E H3F	M4E - Statins H3F - Triptans	99.0% 56.1%	99.6% 93.4%	100.0% 92.2%	100.0% 96.7%	\$14,116,066 \$1,254,559	\$11,947) \$37,731
Dec-02	Oct03, Jul04 Oct03, Apr04,	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	98.8%	97.9%	\$960,890	\$9,441
	Oct04, Jan05	J5D	J5D - Beta Agonists	85.4%	96.0%	95.2%	99.2%	\$2,635,363	\$181,265
	Oct-04 Apr04, Oct04	P5A Q7E/P	P5A - Inhaled Glucocorticoids  Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	77.5% 100.0%	97.7% 100.0%	93.1% 97.5%	98.7% 93.9%	\$3,776,578 \$2,319,622	(\$11,706 (\$17,300
	Oct-04	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	100.0%	100.0%	\$3,595,288	\$53,845
	Dec-02, Mar-04	J5G	J5G - Beta agonists and corticosteroids				100.0%	\$4,064,822.00	(\$59,871
	Mar-04 May-04	A4F W1WXY	A4F - Angiotensin Receptor Blockers W1W/X/Y - Cephalosporins	45.7% 71.7%	88.5% 99.4%	85.8% 91.0%	81.1%	\$1,144,388	\$25,258
		WIW	W1W - Cephalosporins			99.8%	99.8%	\$533,783	\$55,867
Jan-03		VV1X VV1Y	VV1X - 2nd Gen Cephalosporins VV1Y - 3rd Gen Cephalosporins			96.9% 76.3%	96.0% 99.5%	\$259,646 \$2,499,552	\$30,686 (\$316,232
		WID	VVID - Macrolides	99.7%	100.0%	96.7%	98.0% 100.0%	\$3,888,379	(\$363,283 \$52,952
	Oct03, Oct04 Apr-04	W1Q W3B	VV1 Q - Fluoroquinolones VV3B - Antifungals	100.0% 87.4%	100.0% 94.7%	97.9% 92.5%	94.6%	\$3,663,389 \$1,143,603	\$26,476
	Oct03, Jul04, Dec04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	98.4%	91.8%	\$1,929,797	\$44,818
Feb-03	 Jul-04	M9K	M9K - Heparin and Related Products	92.3%	89.0%	99.8%	99.5%	\$1,872,178	\$28,350
	Oct03, Jul04,	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	93.4%	91.4%	\$3,996,045	\$405,039
	Dec04	C4KLM D7L	C4K/L/M - Antidiabetic Agents D7L - Bile Acid Sequestrants	99.1% 50.6%	99.9% 71.2%	98.8% 72.2%	98.9% 76.9%	\$3,341,050 \$134,541	\$263,420 \$2,960
May-03	Apr-04, Dec-04	нза	H3A - Brand Name Narcotics	89.3%	98.1%	98.4%	92.4%	\$18,478,467	\$953,972
	Jun-05 Oct-04	H6H M4E	H6H - Skeletal Muscle Relaxants M4E - Fibric Acids	54.6% 90.9%	95.6% 95.4%	93.7% 95.2%	93.3% 98.7%	\$2,010,910 \$1,316,251	\$153,037 (\$162,419
	Mar-04, Dec-04, Jun-05	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agent	75.7%	98.3%	97.7%	97.9%	\$3,182,170	\$61,984
	Dec-04, Jun-05	J3A	J3A - Smoking Cessation	69.8%	85.1%	84.8%	99.9%	\$473,179	
	Oct03, Jul04	L1B L9B	L1B - Systemic Vit A Derivatives L9B - Topical Vitamin A Derivatives	79.0% 97.9%	81.8% 99.3%				
	Oct-03, Jul-04	L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under)			88.8%	86.0% 0.0%	\$294,603	\$7,414
	Oct-03, Jul-04 Jul-04	L1B/5H/9B L5F, L1A	L1B/L5H/L9B - Acne Agents (over 25) L5F - Antipsoriatics	55.1%	62.3%	0.0% 100.0%	98.6%	\$53,740 \$269,710	\$3,600 (\$1,161
		N1B N1C	N1B - Hematinics N1C - Leukocyte Stimulants	100.0% 80.0%	93.8% 95.7%	100.0% 83.9%	100.0% 83.0%	\$3,969,610 \$457,166	(\$337,505 \$26,348
Jul-03		P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	0.0%	0.0%	\$394,684	(\$12,152
	Mar04, Apr04, Jul04, Jun05	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	79.6%	81.3%	\$1,269,112	\$37,549
	 Jul-04, Dec-04	Q6I Q6R	Q6I - Eye Antibiotic/Corticosteroid Combos Q6R - Eye Antihistamines	14.4% 99.8%	70.4% 100.0%	76.0% 98.9%	77.0% 98.8%	\$44,459 \$144,137	(\$1 (\$6,156
	Oct-03	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	42.4%	93.5%	\$45,323	\$5,673
	Oct03, May04, Oct04	Q6VV	Q6W - Ophthalmic Antibiotics	94.3%	83.7%	98.2%	98.0%	\$352,374	\$5,217
	May-04, Oct-04	Q8VV	Q8FAV - Otic Antibiotics	97.6%	97.9%	99.2%	92.4%	\$439,466	(\$15,949
		D4F	D4F- Anti-ulcer/H.Pylori Agents			0.0%	0.0%	\$48,521	\$3,472
	 Apr-04	Q4F Q4K	Q4F - Vaginal Antimicrobials Q4K - Topical Estrogen Agents	8.7% 100.0%	59.3% 100.0%	67.1% 82.0%	84.0% 86.8%	\$37,947 \$106,218	\$7, <mark>784)</mark> \$1,812
Aug-03	May-04 Oct-03, Oct-04	QSF VV5A	QSF - Topical Antifungal Agents VVSA - Anti-Herpetic Agents	64.0% 41.7%	92.6% 51.6%	83.6% 96.0%	97.3% 97.1%	\$865,417	\$134,759
	Apr-04	W5A	WSA - Anti-Herpetic Agents WSA - Influenza Agents	0.0%	0.0%	0.0%	Jr. 170		
	Apr-04, Dec-04, Mar-05	W5A/H6A	WSA - Anti-Herpetic & Influenza Agents			96.0%	99.9%	\$1,116,184	(\$42,841
Sep-03	Dec-04, Jun-05	D4K-H2A Rx	D4K-H2RA H-2 Antagonists - Rx				95.2% 100.0%	\$2,270,438	\$27,811 \$0
J-03	Dec-04, Jun-05 Jul-04	D4K-H2A OTC S2B	D4K-H2RA H-2 Antagonists - OTC S2B - Cox II's	0.0%	0.0%	0.0%	0.0%	\$35,860 \$3,268,015	\$539,171
May-04	May-04; Oct-04	M4E Other	M4E Other Lipotropic Agents	N/A	N/A	100.0%	100.0% 98.2%	\$1,286,822 \$331,868	(\$447,410 \$15,880
	May-04 Oct-04	R1H A1D	R1H - Inspra (Step Edit: Requires prev.tx w/ spironolactone) A1D - Agents to treat COPD	N/A	NJA	100.0%	98.2% 95.4%	\$331,868 \$3,348,099	\$15,880 \$168,373
Oct-04	Oct-2005, Mar- 05	M4I	M4I - CCB w/HMGs				100.0%	\$85,958	(\$21,481
	Oct-04	W9A	VV9A - Ketolides				0.0%	\$29,693	\$9,120
			TOTAL ALL PDL PROGRAMS	75.2%	95.8%	93.8%	98.7%	\$144,999,032	
		52	Total PDL Classes Studied Totals for Classes With Only Limited Potential For			54	62	Total PDL Clas	ses Studied
		21	Market Share Changes (=>95%)			22	28	\$ 87,558,525	\$1,860,986
		22	Totals for Classes with Substantial Potential For Change (<=94%)			21	19	\$ 57,440,508	
		6	Classes With all Preferred Drugs (100%)			6	10	\$ 41,234,215	
		4	Classes with all NonPreferred Drugs (0%)			54 54	5 62	\$ 3,794,653	. Programs

<u>2<sup>nd</sup> Half Year 3</u>. Based on the analysis of the PDL program for 67 classes between April 1, 2005 and September 30, 2005, ACS estimates the **total 6-month** <sup>39</sup> **net savings after CMS federal rebate reductions to be approximately 9.23 million** (see Table 4.8 and 4.9). After removing cost to administer PDL program the net cost is estimated to be \$8.6 million.

TABLE 4.8. 2<sup>nd</sup> Half Year 3 Estimated Annualized Savings Analysis Summary

	Indiana Medicaid	unzeu buv		
Appubliza		one Voor	<u> </u>	
Annualize	d Estimated Savings Analysis Summ	ary - rear .	•	
Year 2.5 - Count of Therapeutic	Category of Therapeutic Classes	Sept/Oct 04 (End Year 2.5 of PDL Program)	Adjusted Annualized Net Savings Over 32- 37 Months Post- PDL (2.5 Yr of PDL)	Estimated 6 mo Amount Paid Total (Year 2.5 to 3)
Classes		% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates. Contains both state and Federal portion.
67	TOTAL ALL PDL PROGRAMS	95.4%	\$9,225,504	\$128,303,790
22 16	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%) Classes With all Preferred Drugs (100%)			\$90,166,841
<u> </u>	Classes **Ittl all 1 Teleffed Diags (100 70)	<u> </u>		
24	Totals for Classes with Substantial Potential For Change (<=94% or < 95%)	29.0%		\$38,136,950

Source: ACS Government Healthcare Solutions Analysis of OMPP data.

An additional estimated \$ 7.81 million in savings began to be realized in supplemental rebates during this same period.

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<sup>&</sup>lt;sup>39</sup> For Report #4 or  $2^{nd}$  half of Year 3 analysis, because different classes had been operational for different periods of time, and because new quantity limits and other on-going changes occurring during the period studied, the observed results are estimated 6-month figures according to months 32 - 37 of operation (Actual dates were: Apr 1, 2005-Sep 30, 2005) for all classes. Estimates were derived from prescription claims data obtained from OMPP.

TABLE 4.9. 2<sup>nd</sup> Half Year 3 Estimated Savings & Market Share by PDL Class

			Indiana Medicaid PDL Progran	n Evaluat	ion								
				Jan-02 (Before PDL by 7 months)	Sept-03 (End Year 1 of PDL Program)	Sept/Oct 04 (End Year 2 of PDL Program)	Adjusted Annualized Net Savings Over 2nd 12 Months (2nd Yr of PDL)	Annualized Amount Paid Total (Year 2)	Mar 05 (End Year 2.5 of PDL Program)	6-month Amount Paid Total (Year 2 to 2.5)	Adjusted 6- month Net Savings Over 26-31 Months Post-PDL (2 to 2.5 Yr of PDL)		Adjusted 6- month Net Savings Over 32-37 Months Post-PDL (2.5 to 3 Yr of PDL
Original mple- nenta- ion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Pre- ferred	% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates	% Pre-ferred	Prior to Rebates	(Adjusted Annualized Net Savings minus Fed. Rebate)	% Pre- ferred	(Adjusted Annualized Ne Savings minus Fed.Rebate)
Aug-02 Aug-02	Oct03, Jun04 Oct03, Jun04	Z2A Z2A	Z2A - Non-Sedating Antihistamines (RX) Z2A - Non-Sedating Antihistamines (OTC)	24.3%	93.7%	94.1%	\$2,263,851	\$12,792,012	95.0%	\$2,964,955 \$879,547	\$117,245 (\$437,203)	95.0%	\$399,896 (\$414,760)
	Oct03, Jul04 Sep03, Apr04,	A4D	A4D - ACE Inhibitor	33.1%	90.5%	97.5%	\$63,051	\$4,487,225	99.0%	\$2,047,479	\$265,454	99.2%	(\$416,940)
iep-02	Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (RX)	34.9%	82.4%	73.7%	(\$567,862)	\$27,441,018	82.9%	\$12,479,925	\$2,921	81.6%	(\$3,155,399)
	Sep03, Apr04, Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (OTC)						100.0%	\$302,514	(\$156,018)	100.0%	(\$559,846)
	Mar03, Mar05	J7ABC	J7A/BJC - ALPHA/BETA Adrenergic Blockers J7A - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	100.0%	(\$4,493)	\$1,946,456	100.0%	\$1,220,547	\$20,159	100.0%	(\$374,110)
0ct-02	Oct-83		J7C - BETA Adrenergic Blockers J7B - ALPHA Adrenergic Blockers			99.9% 99.5%	(\$25,723) \$1,777	\$4,251,595 \$196,361	100.0% 99.7%	\$2,393,184 \$93,226	\$41,622 \$9,299	100.0% 99.8%	(\$751,709) \$3,158
~~~	Oct-02	A9A	ASA - Calcium Channel Blockers	94.0%	97.6%	98.2%	(\$29,766)	\$10,546,741	97.7%	\$5,292,286	\$145,418	93.8%	(\$1,682,370)
	Oct-02 Oct-02, Dec-04	R1M M9P	R1M - Loop Diuretics MSP - Platelet Aggregation Inhibitors	93.1% 90.1%	99.0% 100.0%	99.8% 98.4%	(\$4,197) (\$13,781)	\$2,092,918 \$12,192,138	99.9% 89.9%	\$1,008,530 \$6,371,035	\$54,246 (\$4,216)	99.9%	(\$337,738) \$4,318,229
	Oct-03, Dec-04 Jul-04, Oct-04	C4N A4D	C4N - Thiazolidenediones A4D - ACE Inhibitor WiDiuretics	52.5% 21.8%	90.1%	98.7% 87.8%	(\$121,660) \$1,778	\$10,005,660 \$474,777	100.0%	\$4,804,426 \$226,028	\$60,985 \$24,745	100.0% 95.4%	(\$1,669,210) (\$45,190)
	Oct-03	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	95.0%	93.1%	\$8,798	\$1,713,257	91.9%	\$943,226	\$19,974	90.3%	(\$273,118)
	Oct-03 Oct03 Mar04,	A4K	A4K - Ace Inhibitor w/CCB	95.2%	99.0%	100.0%	\$1,984	\$1,379,662	100.0%	\$816,181	(\$9,876)	100.0%	(\$289,529)
	May04, Oct04 Apr-04, Oct-04	M4E H3F	M4E - Statins H3F - Triptens	99.0% 56.1%	99.6% 93.4%	100.0% 92.2%	(\$25,315) (\$10,884)	\$27,053,472 \$2,310,830	100.0% 96.7%	\$14,116,066 \$1,254,559	(\$11,947) \$37,731	100.0% 96.3%	(\$4,284,669) (\$179,069)
ec-02	Oct03, Jul04	098	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	98.8%	(\$691)	\$1,808,520	97.9%	\$960,890	\$9,441	98.1%	(\$291,665)
	Oct03, Apr04, Oct04, Jan05	J50	JSD - Betn Agonists	85.4%	96.0%	95.2%	\$296,897	\$9,828,446	99.2%	\$2,635,363	\$181,265		
			JSD - Beta Agonists - Short Acting JSD - Beta Agonists - Long Acting									90.2%	\$831,926 \$192,905
	Oct-04 Apr04, Oct04	PSA Q7E/P	PSA - Inhaled Glucocorticoids Q7EP - Nasal Anti-histomine/Anti-Inflammatory Steroids	77.5% 100.0%	97.7% 100.0%	93.1% 97.5%	\$3,897 (\$3,718)	\$6,609,036 \$4,410,943	98.7% 93.9%	\$3,776,578 \$2,319,622	(\$11,706) (\$17,300)	98.8% 94.3%	(\$172,468) (\$353,283)
	Oct-04	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	99.9%	100.0%	\$476,326	\$32,682,425	100.0%	\$3,595,288	\$53,845	100.0%	(\$741,219)
	Dec-02, Mar-04	J5G	J5G - Beta agonists and corticosteroids						100.0%	\$4,064,822.00	(\$59,871)	100.0%	(\$1,249,193)
	Mor-04 May-04	A4F WIWXY	A4F - Angiotensin Receptor Blockers WIWX/V - Cephalosporins	45.7% 71.7%	88.5% 99.4%	85.8% 91.0%	(\$1,146)	\$1,983,049	81.1%	\$1,144,388	\$25,258	79.1%	(\$241,489)
	May-04	WIW	WIW - Cephalosporins WIW - Cephalosporins	71.7%	99,4%	99.8%	(\$776)	\$1,121,164	99.8%	\$533,783	\$55,967	100.0%	\$119,127
en-03		WIX	W1X - 2nd Gen Cephelosporins W1Y - 3rd Gen Cephelosporins			96.9% 76.3%	\$21,949 (\$39,268)	\$605,519 \$2,818,778	96.0% 99.5%	\$259,646 \$2,499,562	\$30,686 (\$316,232)	94.3%	\$91,270 \$746,756
		WID	WID - Macrolides	99.7%	100.0%	96.7%	(\$31,765)	\$4,704,570	98.0%	\$3,888,379	(\$363,283)	92.5%	\$432,855
	Oct03, Oct04 Apr-04	W1Q W38	W1Q - Fluoroquinolones W3B - Antifungals	100.0% 87.4%	100.0% 94.7%	97.9% 92.5%	(\$213,557) (\$1,910,968)	\$6,388,476 \$2,530,547	100.0% 94.6%	\$3,663,389 \$1,143,603	\$52,952 \$26,476	99.6% 90.5%	(\$258,408) \$161,460
	Oct03, Jul04, Dec04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	98.4%	(\$68,242)	\$3,404,555	91.8%	\$1,929,797	\$44,818	94.0%	\$439,259
eb-03	34-04	M9K P4L	MSK - Heparin and Related Products	92.3% 62.5%	89.0% 95.6%	99.8% 93.4%	\$1,520,082 (\$12,038)	\$3,346,150 \$7,837,621	99.5% 91.4%	\$1,872,178 \$3,996,045	\$28,350 \$405,039	99.6% 89.6%	(\$736,316) (\$1,203,175)
	Oct03, Jul04,		P4L - SERM's Bone Resorption Suppression Agents	99.1%	99.9%	98.8%	(\$102,582)		98.9%	\$3,341,050		99.0%	(\$792,068)
	Dec04	C4KLM D7L	C4K/LM - Antidiobetic Agents D7L - Bile Acid Sequestrants	50.6%	71.2%	72.2%	\$14,737	\$7,096,763 \$250,538	76.9%	\$134,541	\$263,420 \$2,960	75.7%	(\$29,410)
fay-03	Apr-04, Dec-04 Jun-05	H3A. H6H	H3A - Brand Name Narcotics HSH - Skeletal Muscle Relaxants	89.3% 54.6%	98.1% 95.6%	98.4% 93.7%	(\$330,671) (\$73,697)	\$36,088,507 \$4,176,686	92.4% 93.3%	\$18,478,467 \$2,010,910	\$953,972 \$153,037	99.3% 94.2%	(\$5,530,775) (\$474,374)
	Oct-04	M4E	M4E - Fibric Acids	90.9%	95.4%	95.2%	\$43,340	\$2,306,332	98.7%	\$1,316,251	(\$162,419)	90.9%	(\$684,802)
	Mar-04, Dec-04, Jun-05	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Age	75.7%	98.3%	97.7%	(\$44,670)	\$6,166,399	97.9%	\$3,182,170	\$61,984	97.6%	(\$912,734)
	Dec-04, Jun-05 Oct03, Jul04	J3A L1B	JSA - Smoking Cessation L1B - Systemic Vit A Derivatives	69.8% 79.0%	85.1% 81.8%	84.8%	(\$9,744)	\$790,560	99.9%	\$473,179	(\$27,178)	100.0%	(\$147,411)
		LSB	LSB - Topical Vitamin A Derivatives	97.9%	99.3%	00.0%	840.205	#700.070	00.00	#204.000	67.00	00.0%	480 A 400
	Oct-03, Jul-04 Oct-03, Jul-04	L18/9H/98 L18/9H/98	L1BILSHL9B - Acne Agents (Age 25 and under) L1BILSHL9B - Acne Agents (over 25)			88.8% 0.0%	\$19,305 (\$75,700)	\$705,976 \$699,809	86.0% 0.0%	\$294,603 \$53,740	\$7,414 \$3,600	89.6% 0.0%	(\$9,142) (\$5,995)
	Jul-04	LSF, L1A N1B	LSF - Antipsoriatics N1B - Hematinics	55.1% 100.0%	62.3% 93.8%	100.0%	(\$7,869) \$42,735	\$483,398 \$7,654,848	98.6%	\$269,710 \$3,969,610	(\$1,161) (\$337,505)	99.4%	\$3,049,291
ul-03		N1C	N1 C - Leukocyte Stimulants	80.0%	95.7%	83.9%	(\$18,367) \$0	\$1,252,066 \$631,913	83.0%	\$457,166 \$394,684	\$26,348 (\$12,152)	83.3%	(\$76,444) (\$304,081)
	Mar04, Apr04,	P48	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	0.0%			0.0%			0.0%	
	Jul04, Jun05	Q69 Q6I	G6G - Miotics/Other intraocular Pressure Reducers G6I - Eye Antibiotic/Corticosteroid Combos	64.7% 14.4%	75.5% 70.4%	79.6% 76.0%	(\$6,787) (\$3,958)	\$2,585,907 \$91,520	81.3% 77.0%	\$1,269,112 \$44,459	\$37,549 (\$1)	82.7% 77.0%	(\$333,290) (\$3,110)
	Jul-04, Dec-04 Oct-03	QER QEU	G6R - Eye Antihistomines G6U - Ophthalmic Mast Cell Stabilizers	99.8%	100.0%	98.9% 42.4%	(\$3,696) (\$366)	\$300,017 \$128,023	98.8% 93.5%	\$144,137 \$45,323	(\$6,156) \$5,673	95.9% 94.0%	(\$93,586) (\$2,580)
	Oct03, May04, Oct04	QEW	G6W - Ophthalmic Antibiotics	94.3%	83.7%	98.2%	(\$101,146)	\$682,031	98.0%	\$352,374	\$5,217	94.9%	(\$24,809)
	May-04, Oct-04	QBW	QBFAV - Otic Antibiotics	97.6%	97.9%	99.2%	\$33,215	\$942,401	92.4%	\$439,466 \$48,521	(\$15,949)	94.7%	(\$101,221)
		D4F Q4F	D4F - Anti-ulcer/H.Pylori Agents G4F - Vaginal Antimicrobials	8.7%	59.3%	0.0% 67.1%	\$3,859 (\$403)	\$21,614 \$58,480	0.0% 84.0%	\$48,521 \$37,947	\$3,472 (\$7,784)	0.0% 92.6%	(\$13,713) (\$9,552)
	Apr-04 May-04	Q4K Q5F	G4K - Topical Estrogen Agents GSF - Topical Antifungal Agents	100.0%	100.0% 92.6%	82.0% 83.6%	(\$2,350) \$18,217	\$215,240 \$2,150,110		\$106,218 \$865,417	\$1,812 \$134,759	88.5% 98.7%	(\$12,504) (\$245,244)
tug-03	Oct-03, Oct-04	W5A	WSA - Anti-Herpetic Agents	41.7%	51.6% 0.0%	96.0%			97.1%	-	,	75.7%	\$299,460
	Apr-04 Apr-04, Dec-04,	W5A	WSA - Influenza Agents	0.0%	0.0%	0.0%			00.00			99.8%	\$46,978
	Mar-05 Dec-04, Jun-05	WSAMGA D4K-H2A Rx	WSA - Anti-Herpetic 8 Influenza Agents  D4K-H2RA H-2 Antagonists - Rx			96.0%	(\$33,673)	\$1,621,203	99.9% 95.2%	\$1,116,184 \$2,270,438	(\$42,841) \$27,811	87.7% 96.0%	(\$249,893)
Sep-03	Dec-04, Jun-05	D4K-H2A OTO	D4K-H2RA H-2 Antegonists - OTC		6.57	0.00	A107		100.0%	\$35,860	\$0	100.0%	(\$29,538)
	Jul-04 May-04; Oct-04	S2B M4E Other	S2B - Cox Its M4E Other Lipotropic Agents	0.0%	0.0%	0.0%	\$199,691	\$11,892,289	0.0%	\$3,268,015 \$1,286,822	\$539,171 (\$447,410)	100.0%	\$30,609 (\$803,797)
May-04	May-04	R1H	R1H - Inspra (Step Edit. Requires prev.tx w/ spironolactor	N/A	N/A	100.0%	(\$5,031)	\$656,763	98.2%	\$331,868	\$15,880	98.8%	(\$104,304)
0ct-04	Oct-04 Oct-2005, Mer-	A1D	A1D - Agents to treat COPD						95.4%	\$3,348,099	\$168,373	96.5%	\$2,255,354
	05 Oct-04	M4I VV9A	M4I - CCB w/HMGs V/9A - Ketolides						100.0%	\$85,958 \$29,693	(\$21,481) \$9,120	100.0%	(\$172,817) (\$18,767)
			TOTAL ALL PDL PROGRAMS	75.2%	95.8%	93.8%	\$1,128,929	\$298,601,311		\$144,999,032		95.4%	
			TO THE MEET DE PROGRAMS	13.2%	33.0%	00.00 m	71,120,523	72.90,001,311	30.7 %	£1-4,333,63Z			
		52	Total PDL Classes Studied			54	Total PDL Clas	sses Studied	62		Savings Oct04 to Mar05	67	Savings Apr0 to Sep05
			Totals for Classes With Only Limited Potential										
		21	For Market Share Changes (=>95%) Totals for Classes with Substantial Potential			22	\$1,036,467	\$195,966,447	28	\$ 87,558,525	\$1,860,986	22	\$9,225,504
		22 6	For Change (<=94%) Classes With all Preferred Drugs (100%)			21	(\$199,404) \$478,337	\$298,601,311 \$71,857,023	19 10	\$ 57,440,508 \$ 41,234,215		24 16	
		4	Classes with all NonPreferred Drugs (0%)			5	\$127,850			\$ 41,234,215 \$ 3,794,653		16	
`	400		rnment Healthcare Soluti										

<u>1<sup>st</sup> Half Year 4</u>. Based on the analysis of the PDL program for 65 classes between October 1, 2005 and March 31, 2006, ACS estimates the **total 6-month**<sup>40</sup> **net savings after CMS federal rebate reductions to be approximately \$2.94 million** (see Table 4.10 and 4.11). After removing cost to administer PDL program the net cost is estimated to be \$2.27 million.

TABLE 4.10. 1st Half Year 4 Estimated Annualized Savings Analysis Summary

1110111 4.1	Indiana Medicaid			
				_
	Annualized Estimated Savings Analy	sis Sumn		.5
Year 3.5 - Count of Therapeutic	Category of Therapeutic Classes	Mar 06 (End Year 3.5 of PDL Program)	Adjusted Annualized Net Savings Over 38-43 Months Post- PDL (3.5 Yr of PDL)	Estimated 6 mo Amount Paid Total (Year 3.0 to 3.5)
Classes		% Preferred	(Adjusted Annualized Net Savings minus Fed. Rebate)	Prior to Rebates. Contains both state and federal portion.
65	TOTAL ALL PDL PROGRAMS	95.8%	\$2,943,887	\$87,687,213
28	Totals for Classes With Only Limited Potential For Market Share Changes (=>95%)	45		\$63,830,327
	OL MAN UP C LD MCCCC			
17	Classes With all Preferred Drugs (100%)			
	Classes With all Preferred Drugs (100%)  Totals for Classes with Substantial Potential For Change (<=94% or < 95%)	20		\$23,856,886

<sup>&</sup>lt;sup>40</sup> For Report #5 or 1<sup>st</sup> half of Year 4 analysis, because on-going changes occurred during the period studied, the observed results are estimated 6-month figures according to months 38 – 43 of operation (Actual dates of service analyzed were: Oct. 1, 2005-Mar. 31, 2006) for all classes. Estimates were derived from prescription claims data obtained from OMPP.

TABLE 4.11. 1st Half Year 4 Estimated Savings & Market Share by PDL Class

	Indiana	Medicaid	PDL Program Evaluation by Therapeutic C	Class							
				Jan-02 (Before PDL by 7 months)	Sep 05 (End Year 3 of PDL Program)		Change in Pre-ferred % (Sep05 to Mar06)	6-month Amount Paid Total (Year 3 to 3.5) - Oct05 to Mar06	Federal Rebate (Year 3 to 3.5) - Oct05 to Mar06	6-month NET Amount Paid Total (Year 3 to 3.5) - Oct05 to Mar06	Adjusted 6- month Net Savings Ove 38-42 Month Post-PDL (3 to 3.5 Yr of PDL)
Original Imple- menta- tion Date	2nd Year Change Date	Ther Class	PREFERRED DRUGS	% Pre- ferred	% Pre-ferred	% Pre- ferred	Change in Pre-ferred %	Prior to Rebates	Federal Rebate	NET AMT Paid	(Adjusted Annualized Ne Savings minu Fed. Rebate)
Aug-02 Aug-02	Oct03, Jun04 Oct03, Jun04	Z2A Z2A	Z2A - Non-Sedating Antihistamines (RX) Z2A - Non-Sedating Antihistamines (OTC)	24.3%	95.0% 100.0%	59.0% 100.0%	-36.0% 0.0%	\$878,432.28 \$697,606.63	\$168,567 \$18,363	\$709,865 \$679,244	(\$112,042.65 (\$33,849.88
	Oct03, Jul04	A4D	A4D - ACE Inhibitor	33.1%	99.2%	99.3%	0.1%	\$1,200,432.00	\$287,401	\$913,031	\$55,577.19
Sep-02	Sep03, Apr04, Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (RX)	34.9%	81.6%	82.0%	0.3%	\$8,484,967.35	\$3,269,637	<b>\$</b> 5,215,330.37	\$84,471.29
	Sep03, Apr04, Jul04, Dec04	D4K	D4K - Proton Pump Inhibitors (OTC)		100.0%	100.0%	0.0%	\$939,821.41	\$71,913	\$867,908	\$168,443.77
		J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%							
	Mar03, Mar05 Oct-03		J7A - ALPHA/BETA Adrenergic Blockers J7C - BETA Adrenergic Blockers		100.0% 100.0%	99.9% 99.9%	-0.1% -0.1%	\$987,143.04 \$1,630,953.68	\$182,920 \$485,498		\$85,723.97 \$43,154.37
Oct-02			J7B - ALPHA Adrenergic Blockers		99.8%	99.7%	-0.1%	\$44,475.84	\$1,999	\$42,477	\$3,024.81
	Oct-02 Oct-02	A9A R1M	A9A - Calcium Channel Blockers R1M - Loop Diuretics	94.0% 93.1%	93.8% 99.9%	87.9% No longer rev	-5.9% riewed	\$3,164,398.96 No longer review	\$512,082	\$2,652,317 No longer review	\$456,164.35 red
	Oct-02, Dec-04	M9P	M9P - Platelet Aggregation Inhibitors	90.1%	99.8%	99.8%	0.0%	\$4,054,057.31	\$1,328,998	\$2,725,059	\$75,518.28
	Oct-03, Dec-04 Jul-04, Oct-04	C4N A4D	C4N - Thiazolidenediones A4D - ACE Inhibitor W/Diuretics	52.5% 21.8%	100.0% 95.4%	100.0% 99.7%	0.0% 4.3%	\$3,260,620.62 \$118,210.41	\$975,789 \$31,901	\$2,284,832 \$86,309	\$30,738.75 (\$5,372.88
	Oct-03	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	90.3%	96.5%	6.2%	\$656,814.89	\$288,082	\$368,732	\$7,234.92
	Oct-03 Oct03,Mar04,	A4K	A4K - Ace Inhibitor w/CCB	95.2%	100.0%	100.0%	0.0%	\$596,265.94	\$234,078	\$362,188	(\$20,910.36
	May04, Oct04	M4E	M4E - Statins	99.0%	100.0%	100.0%	0.0%	\$9,506,865.14	\$2,901,256		\$226,096.88
	Apr-04, Oct-04	H3F	H3F - Triptans	56.1% 100.0%	96.3% 98.1%	97.9% 100.0%	1.6% 1.9%	\$746,649.36 \$683,869.73	\$220,743 \$242,035	\$525,906 \$441,834	\$50,942.58 \$61,016.29
Dec-02	Oct03, Jul04 Oct03, Apr04,	Q9B	Q9B - Benign Prostatic Hypertrophy Agents		30.176	100.076	1.576	\$000,009.73	\$242,033	Ф441,034	\$61,010.23
	Oct04, Jan05	J5D	J5D - Beta Agonists  J5D - Beta Agonists - Short Acting	85.4%	98.2%	98.6%	0.4%	\$2,260,385.98	\$895,728	\$1,364,658	\$558,909.68
			J5D - Beta Agonists - Long Acting		100.0%	100.0%	0.0%	\$196,305.53	\$84,004	\$112,301	(\$30,728.73
	Oct-04 Apr04, Oct04	P5A Q7E/P	P5A - Inhaled Glucocorticoids Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids	77.5% 100.0%	98.8% 94.3%	97.8% 75.4%	-1.1% -18.8%	\$1,887,220.88 \$1,399,919.26	\$474,127 \$841,698		\$52,732.37 (\$80,664.51
	Oct-04	Z4B	Z4B - Leukotriene Receptor Antagonists	99.8%	100.0%	97.4%	-2.6%	\$1,853,754.42	\$554,276	\$1,299,479	(\$168,081.38
	Dec-02, Mar-04	J5G	J5G - Beta agonists and corticosteroids	15.70	100.0% 79.1%	100.0% 93.5%	0.0% 14.4%	\$2,947,238.02	\$882,063		\$39,468.68
	Mar-04 May-04	A4F W1WXY	A4F - Angiotensin Receptor Blockers W1WXY - Cephalosporins	45.7% 71.7%	79.1%	93.5%	14.4%	\$833,677.06	\$411,319	\$422,359	\$29,553.93
		WIW WIX	W1W - Cephalosporins		100.0%	No Longer Re		No Longer Revie		No Longer Revie	\$151,426.98
Jan-03		WIY	W1X - 2nd Gen Cephalosporins W1Y - 3rd Gen Cephalosporins		94.3% 99.4%	No Longer Re 99.0%	-0.3%	No Longer Revie \$763,095.22	wea \$140,837	No Longer Revie \$622,258	\$246,258.03
		WID	W1D - Macrolides	99.7%	92.5%	94.6%	2.0%	\$1,208,842.93	\$311,097	\$897,746	(\$66,858.18
	Oct03, Oct04 Apr-04	W1Q W3B	W1Q - Fluoroquinolones W3B - Antifungals	100.0% 87.4%	99.6% 90.5%	98.6% 96.3%	-1.0% 5.8%	\$1,846,365.42 \$395,704.91	\$726,238 \$93,362	\$1,120,127 \$302,343	\$63,116.82 \$15,181.75
F 1 00	Dec04	H6J	H6J - Antiemetic/Antivertigo Agents	96.2%	94.0%	96.6%	2.6%	\$1,496,019.69	\$877,274		\$193,770.59
Feb-03	Jul-04	M9K P4L	M9K - Heparin and Related Products P4L - SERM's/Bone Resorption Suppression Agents	92.3% 62.5%	99.6% 89.6%	100.0% 84.5%	0.4% -5.0%	\$1,440,863.30 \$2,354,172.19	\$325,793 \$803,917	\$1,550,256	\$33,217.66 \$60,387.93
	Dec04	C4KLM	C4K/L/M - Antidiabetic Agents	99.1%	99.0%	99.2%	0.3%	\$1,472,566.97	\$195,329	\$1,277,238	(\$80,459.32
	Apr-04, Dec-04	D7L H3A	D7L - Bile Acid Sequestrants H3A - Brand Name Narcotics	50.6% 89.3%	75.7% 99.3%	41.9% 98.1%	-33.8% -1.2%	\$91,732.90 \$11,111,535.41	\$24,369 \$1,932,118	\$67,364 \$9,179,418	\$8,913.54 \$297,597.51
May-03	Jun-05	H6H	H6H - Skeletal Muscle Relaxants	54.6%	94.2%	94.6%	0.3%	\$1,207,258.38	\$85,129	\$1,122,129	\$43,258.71
	Oct-04 Mar-04, Dec-04,	M4E	M4E - Fibric Acids	90.9%	90.9%	72.2%	-18.7%	\$932,155.91	\$147,837		\$44,334.93
	Jun-05	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Agen	75.7%	97.6% 100.0%	96.6% 99.7%	-1.0%	\$1,903,337.53 \$467,054.09	\$531,656 \$38,919		\$30,267.50
	Dec-04, Jun-05 Oct03, Jul04	J3A L1B	J3A - Smoking Cessation L1B - Systemic Vit A Derivatives	69.8% 79.0%	100.0%	99.7%	-0.3%	\$407,004.09	\$30,313	\$428,135	\$47,467.40
		L9B	L9B - Topical Vitamin A Derivatives	97.9%	00.00	05.704	0.400		****	200 057	/200 00F 0
	Oct-03, Jul-04 Oct-03, Jul-04	L1B/5H/9B L1B/5H/9B	L1B/L5H/L9B - Acne Agents (Age 25 and under) L1B/L5H/L9B - Acne Agents (over 25)		89.6% 0.0%	95.7% 0.0%	6.1% 0.0%	\$103,014.73 \$30,760.64	\$33,958 \$8,345	\$69,057 \$22,416	(\$30,835.07 (\$2,646.10
	Jul-04	L5F, L1A	L5F - Antipsoriatics	55.1%	99.4%	100.0%	0.6%	\$184,429.82	\$79,305	\$105,125	(\$2,756.47
		N1B N1C	N1B - Hematinics N1C - Leukocyte Stimulants	100.0% 80.0%	100.0% 83.3%	100.0% 100.0%	0.0% 16.7%	\$3,452,498.72 \$359,388.83	\$1,261,825 \$160,992		\$180,909.39 \$20,584.50
Jul-03		P4B	P4B - Bone Formation Stimulating Agents	0.0%	0.0%	0.0%	0.0%	\$281,409.00	\$74,080		\$16,840.16
	Mar04, Apr04, Jul04, Jun05	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	82.7%	87.3%	4.6%	\$716,892.28	\$229,108		\$12,295.11
		Q6I	Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	77.0% 95.9%	85.2% 98.4%	8.2% 2.6%	\$21,570.95	\$10,995 \$62,722		(\$2,370.19
	Jul-04, Dec-04 Oct-03	Q6R Q6U	Q6R - Eye Antihistamines Q6U - Ophthalmic Mast Cell Stabilizers	99.8% 20.7%	95.9%	98.4%	0.1%	\$143,408.54 \$10,857.12	\$62,722 \$4,608		(\$13,824.88 (\$2,768.15
	Oct03, May04, Oct04	Q6W	Q6W - Ophthalmic Antibiotics	94.3%	94.9%	98.6%	3.8%	\$118,593.75	\$26,549		(\$25,980.88
	May-04, Oct-04	Q8VV	Q8F/W - Otic Antibiotics	97.6%	94.7%	95.4%	0.7%	\$144,271.42	\$22,635	\$121,636	(\$77,762.60
	-	D4F	D4F- Anti-ulcer/H.Pylori Agents Q4F - Vaginal Antimicrobials	0.70	0.0%	0.0%	0.0%	\$25,434.10 \$49,892.23	\$10,516 \$10,691		(\$6,625.68 \$5,007.97
	 Apr-04	Q4F Q4K	Q4F - Vaginal Antimicrobials Q4K - Topical Estrogen Agents	8.7% 100.0%	92.6% 88.5%	90.2% 97.4%	-2.4% 8.9%	\$49,892.23 \$66,984.94	\$10,691 \$43,231	\$39,201 \$23,754	\$5,227.97 \$219.28
	May-04	Q5F	Q5F - Topical Antifungal Agents	64.0%	98.7%	99.1% 97.6%	0.4%	\$458,731.21	\$38,551 \$83.051	\$420,180 \$60,641	(\$8,405.40 (\$4,549.10
Aug-03		W5A W5A	W5A - Anti-Herpetic Agents W5A - Influenza Agents	41.7% 0.0%	75.7% 99.8%	97.6% 100.0%		\$143,692.70 \$81,879.17	\$83,051 \$9,480	\$60,641 \$72,399	\$4,549.10 \$7,660.82
Aug-03	Oct-03, Oct-04 Apr-04	440M									
Aug-03	Apr-04 Apr-04, Dec-04,				87.7%						
Aug-03	Apr-04	W5A/H6A	W5A - Anti-Herpetic & Influenza Agents D4K-H2RA H-2 Antagonists - Rx		87.7% 96.0%	91.5%	-4.4%	\$1,109,645.23	\$206,771	\$902,874	(\$100,675.48
Aug-03 Sep-03	Apr-04 Apr-04, Dec-04, Mar-05 Dec-04, Jun-05 Dec-04, Jun-05	W5A/H6A D4K-H2A Rx D4K-H2A OTC	W5A - Anti-Herpetic & Influenza Agents D4K-H2RA H-2 Antagonists - Rx D4K-H2RA H-2 Antagonists - OTC		96.0% 100.0%	100.0%	0.0%	\$20,680.79	\$884	\$19,797	(\$3,930.99
Sep-03	Apr-04 Apr-04, Dec-04, Mar-05 Dec-04, Jun-05 Dec-04, Jun-05 Jul-04	W5A/H6A D4K-H2A Rx D4K-H2A OTC S2B	W5A - Anti-Herpetic & Influenza Agents D4K-H2RA H-2 Antagonists - Rx D4K-H2RA H-2 Antagonists - OTC S2B - Cox II's	0.0%	96.0% 100.0% 0.0%	100.0% 0.0%	0.0% 0.0%	\$20,680.79 \$1,054,256.43	\$884 \$317,942	\$19,797 \$736,315	(\$3,930.99 (\$9,562.48
_	Apr-04 Apr-04, Dec-04, Mar-05 Dec-04, Jun-05 Dec-04, Jun-05 Jul-04 May-04; Oct-04 May-04	W5A/H6A D4K-H2A Rx D4K-H2A OTC S2B M4E Other R1H	W5A - Anti-Herpetic & Influenza Agents D4K-H2RA H-2 Antagonists - Rx D4K-H2RA H-2 Antagonists - OTC S2B - Cox II's M4E Other Lipotropic Agents R1H - Inspra (Step Edit Requires prev.b.w/ spironolacton		96.0% 100.0% 0.0% 100.0% 98.8%	100.0% 0.0% 100.0% 98.3%	0.0% 0.0% 0.0% -0.5%	\$20,680.79 \$1,054,256.43 \$1,572,721.72 \$219,645.82	\$884 \$317,942 \$463,263 \$12,618	\$19,797 \$736,315 \$1,109,459 \$207,028	(\$3,930.99 (\$9,562.48 \$158,483.14 \$15,596.40
Sep-03 May-04	Apr-04 Apr-04, Dec-04, Mar-05 Dec-04, Jun-05 Dec-04, Jun-05 Jul-04 May-04; Oct-04 May-04	W5A/H6A D4K-H2A Rx D4K-H2A OTC S2B M4E Other R1H A1D	W5A - Anti-Herpetic & Influenza Agents D4K:H2RA H-2 Antagonists - Rx D4K:H2RA H-2 Antagonists - OTC S2B - Cox III' M4E Other Lipotropic Agents R1H - Inspira (Step Edit Requires prev.bt.w/ spironolacton A1D - Agents to treat COPD		96.0% 100.0% 0.0% 100.0% 98.8% 96.5%	100.0% 0.0% 100.0% 98.3% 97.0%	0.0% 0.0% 0.0% -0.5% 0.6%	\$20,680.79 \$1,054,256.43 \$1,572,721.72 \$219,645.82 \$2,390,913.69	\$884 \$317,942 \$463,263 \$12,618 \$928,415	\$19,797 \$736,315 \$1,109,459 \$207,028 \$1,462,499	(\$100,675,46 (\$3,930,99 (\$9,562,48 \$158,483,14 \$15,596,40 \$123,030,05
Sep-03	Apr-04 Apr-04, Dec-04, Mar-05 Dec-04, Jun-05 Dec-04, Jun-05 Jul-04 May-04; Oct-04 May-04	W5A/H6A D4K-H2A Rx D4K-H2A OTC S2B M4E Other R1H	W5A - Anti-Herpetic & Influenza Agents D4K-H2RA H-2 Antagonists - Rx D4K-H2RA H-2 Antagonists - OTC S2B - Cox II's M4E Other Lipotropic Agents R1H - Inspra (Step Edit Requires prev.b.w/ spironolacton		96.0% 100.0% 0.0% 100.0% 98.8%	100.0% 0.0% 100.0% 98.3%	0.0% 0.0% 0.0% -0.5%	\$20,680.79 \$1,054,256.43 \$1,572,721.72 \$219,645.82	\$884 \$317,942 \$463,263 \$12,618	\$19,797 \$736,315 \$1,109,459 \$207,028 \$1,462,499	(\$3,930.99 (\$9,562.48 \$158,483.14 \$15,596.40

## **Grand Total from PDL Implementation to Year 4**

An additional estimated \$ 6.08 + 7.81 + 7.59 million = \$21.48 million in savings began to be realized from October 1, 2004 to September 30, 2005 in supplemental rebates. The grand total net pharmacy benefit savings representing total net expenditures projected had the PDL program not been instituted less federal rebate changes and minus cost to administer the program plus supplemental rebates is estimated to be approximately \$41.38 million from August 2002 to March 2006.

Table 4.12 Number of Classes, Rebate Shifts & Estimated Savings<sup>41</sup>

Time Period	# Classes Affected by the PDL Program	Total Estimated Savings from Market Share Shifts <sup>42</sup> before Rebates	Total Estimated Rebate Shifts	Total Net Savings <sup>43</sup> Estimates Minus Federal Rebate Estimates	Estimated Cost of Administering the PDL	Total Net Savings <sup>44</sup> Estimates Minus Rebates & Estimated Cost of Administering the PDL
Year 1 (8/1/02 to 7/31/03)	52	\$12.4 million	- \$3,524,829	\$8.9 million	-\$1.125 million	\$7.78 million
Year 2 (10/1/03 to 9/30/04)	54	\$2.06 million	- \$ 931,105	\$1.13 million	-\$1.125 million	\$ 175,000
1 <sup>st</sup> half Year 3 (10/1/04 to 3/31/05)	62	\$1.99 million	- \$ 130,139	\$1.86 million	-\$614,000	\$1.25 million
2 <sup>nd</sup> half Year 3 (4/1/05 to 9/30/05)	67	\$ 10.96 million	- \$1,731,412	\$9.23 million	-\$627,500	\$8.60 million †
1 <sup>st</sup> half Year 4 (10/1/05 to 3/31/06)	65**	\$4.53 million	-1,589,078	\$2.94 million	-\$675,000	\$2.27 million
SubTotal		\$31.94 million	\$7,906,563 million	\$24.06 million	-\$4.165 million	\$19.9 million
Supplementa	l Rebate Sa	vings (10/1/04 to	3/31/05)	\$6.08 millio	n*	
Supplementa	al Rebate Sa	avings (4/1/05 to	9/30/05)	\$7.81 millio	on	+ \$21.48 Million
Supplementa	ıl Rebate Sa	on				
GRAND TOT	AL Net Savi	\$41	I.38 Million			

<sup>&</sup>lt;sup>41</sup> All savings and net savings are estimated.

<sup>&</sup>lt;sup>42</sup> Estimates include both state and federal share.

<sup>&</sup>lt;sup>43</sup> Estimates include both state and federal share.

<sup>&</sup>lt;sup>44</sup> Estimates include both state and federal share.

<sup>\*</sup> Report #3 reported supplemental rebate savings as \$6.81 million. After all adjustments were made, the supplemental rebate savings changed to \$6.08 million; therefore, supplemental rebate savings were adjusted accordingly in Report #4.

Total therapeutic classes reviewed dropped from 67 to 65 classes because one class was split into two classes & three classes were no longer reviewed from Study 4 to 5).

## **Conclusions on PDL Program Savings**

The Indiana Medicaid Preferred Drug List Program as implemented and evaluated through March 31, 2006 involved 65 therapeutic classes. In year one, the program succeeded in increasing the share of preferred drugs relative to their non-preferred alternatives from 75.2% in January 2002 to 95.8% by September 2003. In year two, the program succeeded in retaining market share at 93.8% preferred drugs dispensed, increased by the 1<sup>st</sup> half of year 3 to 98.7% preferred drugs dispensed, and then decreased slightly to 95.8% preferred drugs dispensed by March 2006.

The pharmacy net savings resulting from implementing a PDL program were estimated to be \$7.78 million in Year 1, an additional \$175,000 in Year 2, an additional \$1.25 million over 6-months from Year 2 to 1<sup>st</sup> half of Year 3, an additional \$8.6 million over 6-months from 1<sup>st</sup> half to 2<sup>nd</sup> half of Year 3, and an additional \$2.27 million over 6-months from 2<sup>nd</sup> half of Year 3 to 1<sup>st</sup> half of Year 4. This figure does not include additional estimated savings of \$21.48 million from supplemental rebates added beginning in October 2004 through March 2006.

Over the 3.5-year period after implementation of the PDL program, the overall net pharmacy savings are estimated to be \$19.9 million plus approximately \$21.48 million in supplemental rebates for an estimated total savings since implementation of approximately \$41.38 million.

The program included many therapeutic classes with very limited opportunities for shifting from non-preferred to preferred medications. Some of these classes experienced cost increases rather than cost savings because of changes among the preferred medications. The program also included several classes where the net costs for the preferred medications were greater than the net costs of the non-preferred drugs. In those classes, the preferred drugs were considered clinically superior and safer than the lower cost drugs in the class. Shifting a prescription from non-preferred to preferred in those classes increased the net cost.

Given the ability of the PDL program to increase preferred drug market share, the choice of therapeutic classes with opportunities for such shifts and the selection of the most cost-effective drugs as preferred were crucial to fully realizing the potential financial benefits of the preferred drug list. The selected drugs must be clinically appropriate to the needs of the target population and the expected net cost (expected payment amount per claim less expected rebate amount per claim) of preferred drugs must be lower than that of the non-preferred drugs that they are likely to be replacing. It is necessary to consider both the price paid to pharmacies and the federal rebates received from manufacturers in assessing relative net costs. If the average net cost for preferred drugs in a class is more costly than the non-preferred drugs, then shifting to preferred drugs increases rather than decreases costs.

To produce substantial savings with a preferred drug list, it is also important to limit the number of drugs deemed as "preferred." Overly inclusive lists limit savings since they reduce the number of non-preferred drug prescriptions eligible for change. In addition, the excluded AAAX drugs should be considered as part of the PDL since their percentage of the overall cost will continue to climb.

## **Limitations of the Savings Estimation Methodology**

There is nothing inherent in the design of a preferred drug program that causes overall utilization increases. The program does not promote the new use of particular drugs (i.e., a PDL is not intended to encourage the use of a drug that has not been previously in use) rather an intervention occurs when a prescription for a non-preferred drug is being processed. At this point in time, the non-preferred medication may be dispensed, the prescription may be changed to a preferred medication, or the therapy may be terminated. Thus, there is the intrinsic possibility of some utilization decline in association with a PDL intervention. If there is any decrease in utilization, the calculated savings will decline accordingly. If the reduction in utilization is due to reduction of inappropriate utilization by the PDL intervention, then there are real utilization savings for the State in the form of fewer overall claims. This methodology does not adjust the PDL savings estimates to capture such program savings. It is very difficult to discern the extent to which any observed reduction in utilization in a PDL class was due to the intervention or to other factors. Therefore, the estimates presented may underestimate the program savings. Additionally, if prescribing practitioners switch their patients to the preferred drug, or start prescribing the preferred drug before the implementation of each PDL phase, the methodology does not capture the potential savings.